University Of Alberta

APPLICATION OF SENSORS IN THE CONTROL OF FUNCTIONAL ELECTRICAL STIMULATION

by

RONGCHING DAI ©

A thesis submitted to the Faculty Of Graduate Studies and Research in partial
fulfillment of the requirements for the degree of

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Division of Neuroscience

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To Whom It May Concern:

Chapter 2 and 3 of the thesis by Rongching Dai contains material that was published as multi-authored studies. He included the material that he was mainly responsible for. I and the other co-authors have no objection to him including this material in the thesis.

Sincerely yours,

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ABSTRACT

Sensors play a vital role in closed-loop control of Functional Electrical Stimulation (FES). Two efforts are made in this study to identify the suitable sensors for improving FES control of walking. In the first project, a method is developed for using peripheral neural recordings to control the stimulation to the extensors and flexors of the ankle joint of the hindlimb during walking in a cat model. Whole nerve signals from the tibial (TI) and superficial peroneal (SP) nerves are recorded with chronically implanted nerve cuffs. With threshold detection and a 4-state rule-base, we are able to use the TI and SP signals to trigger the stimulation to the extensor when the paw touches the ground and to the flexor when it lifts off. The use of signals from intact nerves may promise an unmatched sensor source and fully implantable systems. In the second project, Tilt sensors are studied for their properties in measuring the angular displacement of leg segments during gait. A finite state approach allows the sensor attached to the shank to effectively detect the step intention in a population of stroke and incomplete SCI subjects and to control the FES. We have designed a miniature footdrop stimulator with a magnetoresistive tilt sensor built into it, so that there are no external sensor cables involved. This device features several advantages over an AFO or footswitch controlled stimulator. Improvement of gait is observed in two incomplete SCI subjects and one stroke subjects who have used the newly designed foot drop stimulator in early testing trials, as well as in those who have used a variety of simple stimulation systems for walking for over periods from 1 to 4 years.

PREFACE

Functional Electrical Stimulation (FES) is a research and application field that challenges everyone who touches it. I have had the opportunity to study and get the guidance from some of the leading scientists in this field. I have touched several topics during the three and a half years, but the main topic is sensors in the control of FES. This thesis is composed of three projects that are related to this topic.

In the first chapter, a literature review is made, on my best understanding, on the control problems of an FES-human system, the role of sensors in this business, and the current status of development and implementation of natural and artificial sensors. Recording from the peripheral sensory nerves with cuff electrodes and using the signals to control FES systems has been an inspiring topic because using intact nerve bundles as natural sensors eliminate the battery, mounting and cosmesis problems altogether. I was very fortunate to have the opportunity to participate in such a research project from monitoring the electrodes and recording to deriving the control signals with Dr. Stein who pioneered this field and some of my colleagues. As a result, the project was published in IEEE Transactions on Biomedical Engineering. The part I was involved is presented in Chapter 2. I should acknowledge that this was a joint effort with Dr. Stein, Dr. Popovic and my colleague Ms. Jovanovic. The search for suitable sensors also lead us to the tilt sensors. In Chapter 3, the properties of several types of tilt sensors are described and an implementation in controlling the FES is discussed. This investigation has lead to the development of the WalkAid stimulator (Biomotion, Inc.) that uses a built-in tilt sensor and promises a better cosmesis and robustness. The preliminary testing result on incomplete SCI and stroke subjects who had a foot drop problem is presented in Chapter 4. A formal clinical evaluation is also proceeding in Edmonton (Naaman's thesis, 1996).

For the past three years I also participated in the cross Canada program of “multi-center clinical testing of stimulation systems for walking”. In the first part of Chapter 4, I present the result of gait analysis on the 6 subjects using different FES systems from Edmonton area during the three years. Although it seems apart from the theme, I felt it as an integrated part of my program that helps me better understanding the importance and problems of FES.

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Also, my thanks to the student training committee of the Neuroscience Network of Centres of Excellence for providing me the financial support for my study in neuroscience.

I would like to dedicate this thesis to my mother: you are always my spiritual support.

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1. INTRODUCTION

1.1 FES for restoring lower extremity function

Human standing and locomotion is achieved by coordinated muscle activities. This involves complicated control mechanisms of the nervous system. The central nervous system (CNS) sends control signals through the spinal cord and efferent nerve fibers to contract the extensor and flexor muscles at joints to support the posture and/or take a step, while various sensors feed back information of muscles, limbs and the body through afferent nerve fibers, helping to regulate the limb movement and respond to external disturbances through CNS and spinal reflexes. The central and local mechanisms allow the CNS to control the muscle activity adaptively during standing, walking and other limb movement.

Following a spinal cord injury (SCI) or cerebrovascular accident (CVA) such as a stroke, head injury or multiple sclerosis, neural pathways between the CNS and the muscles may be partially or completely severed. This often results in complete or incomplete muscular paralysis and loss of feedback sensations which usually lead to hemiplegia or paraplegia. Mechanical orthosis, walking aids and wheelchairs have been used to help regain some standing, walking and mobility. In many cases, the subjects have an intact or partially intact peripheral nervous system and the muscles remain innervated. For such subjects, electrical stimulation may be used to functionally resume the impaired mobility by artificially activating the neurally intact muscles with controlled electrical pulses. Functional electrical stimulation (FES) is the use of lower level electrical stimulation to facilitate functional control [56]. Besides restoration of mobility, FES has also been used to restore other functions such as respiratory control and urinary control, and for therapeutic purposes such as muscle strengthening and spasticity releasing. The goal of FES for standing and walking is to improve mobility and reduce energy expenditure. Although a neural pathway may not be replaced artificially, an paralyzed individual may still benefit from such a functional system. If for example a lower limb FES system merely restores a few basic tasks, e.g., rising from a chair, standing, level walking and/or limited climbing and descending, an otherwise wheelchair-bound complete SCI individual may not only improve his or her functioning in daily life, but also his or her physiological condition in many aspects, such as improved cardiopulmonary fitness and retention of muscle integrity, etc. [42,61].

In basic realizations an FES system converts command inputs directly from the subject into electrical stimuli that are applied to the paralyzed extremity to elicit a step or maintain a posture, which can be expressed as shown in Figure 1-1. This supervisory control assumes intact visual, vestibular and proprioceptive sensibilities to ensure that proper commands be given by the subjects [6,43]. Due to long latencies of the control loop, the use of high frequency and high level stimuli, the nonlinear and time varying muscle output property, etc., this scheme is prone to poor stability and fast muscle fatigue. Some potential

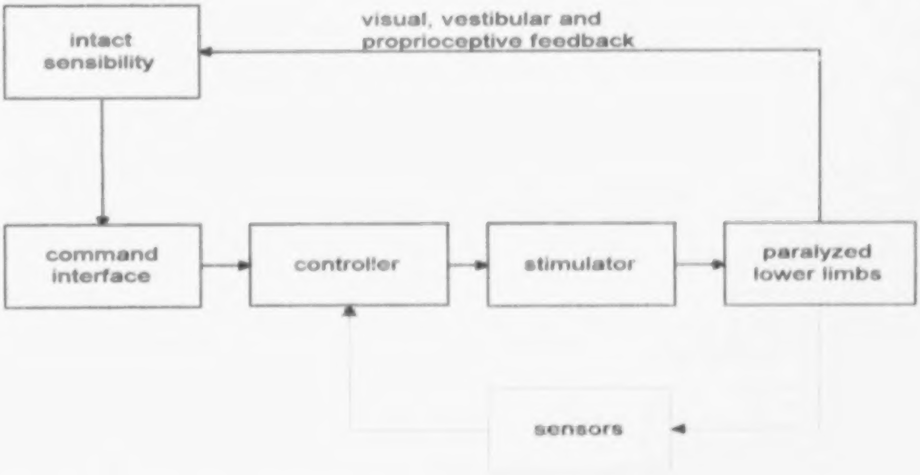


Figure 1-1. A basic realization FES systems with supervisory control. The subject direct the commands to turn on and off the stimulator based on the visual, vestibular and proprioceptive information through the intact sensibility. Feeding back the information directly to the controller via sensors makes a closed-loop controller.

solutions to improve the performance of the FES systems include one or a combination of the following: 1) improved FES-neuromuscular interface such as selective activation of different muscle groups during different tasks via multichannel stimulation; 2) improved control method incorporating closed-loop control. In addition to these problems, a practical usable system requires good reliability, robustness, ease of use and good cosmesis, i.e., it has to yield net functionality.

The FES-neuromuscular interface is realized with electrodes and the pattern of stimulation they deliver. The main problems with the FES-neuromuscular interface are poor selectivity, reversed activating order of nerve fibers and high frequency stimulation used, which all lead to fast muscle fatigue. Electrodes are responsible for stimulation selectivity. They can be categorized into three groups. They are surface electrodes for transcutaneous stimulation; percutaneous or intramuscular electrodes for subcutaneous stimulation and implanted electrodes for direct nerve stimulation.

Surface electrode technique is noninvasive and most widely used in clinical applications. A surface single channel stimulator was the very first FES system introduced by Liberson to correct foot drop in hemiparetic subjects [45]. This system is suitable for stroke subjects and a limited population of incomplete SCI subjects who have sufficient voluntary control. The single channel stimulation is generally delivered to activate the dorsiflexors to lift the foot and/or also to the sensory fibers of the common peroneal nerve to elicit a flexion reflex for a hip flexion during the swing phase. A minimum of four channels of stimulation are required for ambulation of a complete paraplegia with preserved balance and upper body control [42]. Stimulation is applied to the quadriceps muscles of both sides to lock the knee during standing, and to the common peroneal nerve on the ipsilateral side to initiate a step through the flexion reflex. The major problems of transcutaneous stimulation are the poor muscle selectivity, unstable relation between stimulus and elicited muscle contraction, variable day-to-day electrode placing sites and pain sensation in some stroke subjects.

Percutaneous electrodes improve the selectivity and provide the possibility to activate many different muscle groups. But the selectivity and efficiency of intramuscular electrodes depends on the placement and electrode configuration (bipolar or monopolar) [65]. wires are usually placed close to the motor point within selected muscles. A multichannel percutaneous system usually achieves a better gait performance than surface systems (see chapter 4). A 48 channel system was suggested to achieve a reasonable walking pattern for a complete SCI subject. The major problems with percutaneous electrodes are infection, wire breakage and wire encapsulation. Using reinforced wires improves the electrode life [68].

Fully implanted systems with direct nerve stimulation avoid many of the major problems with surface and percutaneous stimulation. Some single channel fully implanted peroneal stimulator functioned over 20 years [78]. Nerve stimulation is usually realized with cuff electrodes and offer better selectivity over other methods. The selectivity might be further improved with multipolar cuff electrodes [52,85,90] and intrafascicular electrodes [52,100], with the multipolar cuff electrodes being the most promising [52]. A fully implantable multichannel system still needs to solve problems such as power supply, encapsulation and biocompatability.

Incorporating feedback of kinematic information from the stimulated limb directly to the controller could also improve the performance of the FES system. This closed-loop control allows automated adjustment of stimulation according to the condition of the limb and/or the stimulated muscles. The feedback of the limb information is realized with sensors, as shown in Figure 1-1. Two feedback approaches exist: one based on natural sensors as a source of control signals [24,30,82] and another on artificial sensors [14]. The performance of closed-loop control depends on the quality of the sensors fulfilling the control method. In practical FES systems, *using a closed-loop scheme may improve its* *performance ONLY if there are suitable sensors.* The theme of this thesis is *investigating sensors suitable for the closed-loop control of lower extremity FES systems.*

1.1.1 Application of FES to restore locomotion in SCI subjects

For SCI individuals with some voluntary limb muscle abilities, simple surface or implanted FES systems have proven feasible in improving gait performance and quality. Due to the increasing safety standards and the advancement of emergency treatment, the proportion of incomplete spinal cord injuries has significantly increased among the total SCI population [21,42]. The benefits of an FES program to SCI subjects have been assessed in a number of aspects. Through FES treatment with simple systems, most subjects experienced functional improvement of both gait parameters such as walking speed, stride length and the physiological cost of gait [8,21,78]. In other observations, an FES gait program also resulted in a reduction in quadriceps' tone and spasticity and an increase in voluntary muscle strength [21,91]. Some subjects have switched from using mechanical bracing to FES. Other subjects have progressed from using crutches to cane, and to no need for aids [78]. FES systems were mainly one to four channel devices with either hand or foot switches. In most cases, stimulation is only conducted to the common peroneal nerve to facilitate the gait by the flexion withdrawal reflex mechanism. With percutaneously implanted electrodes, which have a greater selectivity, several muscle groups are usually stimulated in order to achieve a better gait pattern without concerning the skin's pain receptors. Gait progress has however been different for different SCI subjects, some more significant than others [21,78]. This necessitates individual strategies and fine tuning for different individuals with more subjects and testing to identify the influence of various possible mechanisms related to the FES assisted gait; e.g., bracing, electrode placement, automatic operation and the number of channels, etc. As well as the functional concerns, cosmetic factors are also an important consideration. As the proportion of incomplete SCI individuals among the whole SCI population have been steadily increasing, clinical implementation of FES in this area remains challenging.

For FES assisted ambulation of SCI paraplegics who have lost control to both lower extremities, a minimum of four channels of surface stimulation is required, with the stimulation of the quadriceps for knee extension in the stance phase and stimulation of the common peroneal nerve for initiation of the swing phase by the flexion withdrawal reflex [22,42]. Sufficient arm strength must be available in this situation to provide balance with walking aids, such as a rolling walker, crutches or parallel bars: The stimulation with preset parameters is usually initiated through hand switches. Some limiting factors have been identified involving FES assisted gait of paraplegics; e.g., fast muscle fatigue resulting from stimulation, poor gait performance and poor disturbance rejection associated with inefficient trunk and limb control from FES systems, etc. [42,47,92]. To improve FES assisted gait qualities, a number of FES protocols have been developed or proposed. These protocols include multichannel percutaneous systems, selective nerve activation electrode technologies, and hybrid systems, etc.. The reported 48 channel percutaneous systems may for example provide FES control of the spine, hip, knee and ankle joints with preprogrammed stimulation patterns [47]. Although the subjects using this system reached a steady walking speed of 0.6 meters per second (m/s), over a maximum 1200 meter distance in the laboratory environment, the technical complexity, stability and high energy cost may hinder the clinical implementation [36]. A hybrid FES system is another protocol being extensively investigated. The hybrid FES systems combine surface FES with mechanical bracing that is used to stabilize the lower extremities during the stance phases. The use of mechanical braces effectively reduces the energy expenditure, increases safety, reduces the degree of freedom and therefore simplifies the control mechanism [2,62]. The hybrid system that uses a pair of below knee floor reaction orthoses is for example able to support standing of a paraplegic subject for an hour without greatly fatiguing the limb muscles [3].

1.1.2 Application of FES for improving hemiplegic gait

FES was first introduced by Liberson et al to improve gait function in 1961 [45]. The first people to receive FES were all hemiplegic subjects who had suffered foot drop. A single channel stimulation was applied to the common peroneal nerve to initiate a step by the elicited flexion withdrawal reflex. In order to synchronize the stimulation of the peroneal nerve with the gait phase, a foot switch was introduced in the sole of the shoe so that as soon as the subject lifted his or her foot off the ground, a dorsiflexion was triggered by the stimulator.

Hemiplegia is one of the common disabilities of the modern world, affecting two to three people per thousand [76]. The dominant causes of hemiplegia are stroke, head injury and brain trauma. Kralj (1993) reported that up to 63% of annual cases are candidates for an FES based therapeutic locomotion rehabilitation program in Ljubljana [41]. FES applied to hemiplegic patients for gait assistance with long term use has mainly been single channel peroneal stimulators like that proposed by Liberson, both surface and implanted versions. The single channel stimulator has gained good patient acceptance because of its simplicity of use and reliability. Multichannel programmable stimulation has also been applied to different muscle groups during swing and stance phases with the aim of gaining a better and faster correction of hemiplegic gait before switching to a single channel device for a long term use [41]. Limited number of implantable peroneal stimulators have been applied to avoid problems with daily positioning of surface electrodes and skin reactions [38,84,93]. Clinical follow up of implanted subjects has shown that gait parameters were improved significantly, although in some subjects electrode displacement resulted in reimplantation after an average time of 3.5 years of proper functioning [38]. They have regained attention because of the advancement of powerful microprocessors and expectations for new technology in implant power supply, electrode-tissue interface, and particularly, both robust artificial sensors and interfacing natural sensors as implantable footswitches.

1.2 The role of sensors in FES control

1.2.1 Open-loop control systems

An FES system can operate in open-loop in which no sensory feedback is involved. A lower extremity FES system may use a hand switch to turn on and off one or more channels of stimuli to elicit a gait movement. In the 4 channel system described by Kralj and Bajd, for example, the paraplegic subjects manually switch on the stimulation to the peroneal nerves to elicit a withdraw reflex in swing phase and switch on stimulation to the quadriceps to lock the knee in stance phase [42]. For hemiplegic subjects who have considerable voluntary control of one or both legs, a footswitch in the ipsi- or contra-lateral side is usually used to trigger the stimulation [41,45,67,93]. A footswitch is however more likely to be considered as a feedback sensor for the stimulation-gait system. The stimulation levels are determined through clinical experience on a trial-and-error basis. In more sophisticated systems the stimulation pattern for each muscle group is modeled on the average EMG pattern in normal subjects [24,47,49,50,57]. They are either prestored or directly calculated on execution. The open-loop control method has been used in upper extremity FES systems in which artificial sensors are difficult to mount and preserved sensory ability such as visual feedback can be used by the subjects.

In the open-loop systems, sensors are needed to interface volitional commands to the stimulator in situations where handswitches are not applicable or practical. The volitional control signal can be from head, shoulder or wrist position, sound, respiration, EMG activity, etc. [24,25,31,35,57]. Most of these applications are for upper arm or hand control. For a lower extremity FES system, a handswitch may provide better security [14].

1.2.2 Closed-loop control systems

Although in some subjects an open-loop FES system might provide enough function for daily life, using preprogrammed or precalculated stimulation patterns, either by trial-and-error or by modeling, is likely to be inadequate to produce smooth movement for severely paralyzed extremities. This results from the fact that muscle outputs are highly nonlinear, electrically stimulated muscles tend to fatigue early so that their properties vary with time, paralyzed individuals are usually subject to abnormal conditions such as spasticity, clonus, joint contracture, modified reflexes, etc. [63,77,83]. The open-loop performance is worsened when using transcutaneous stimulation through surface electrodes by the high intra- and inter-subject variability originating in the relation between stimulation input and contraction effect. In addition, any unexpected external disturbances in daily life such as change of external load or terrain for walking

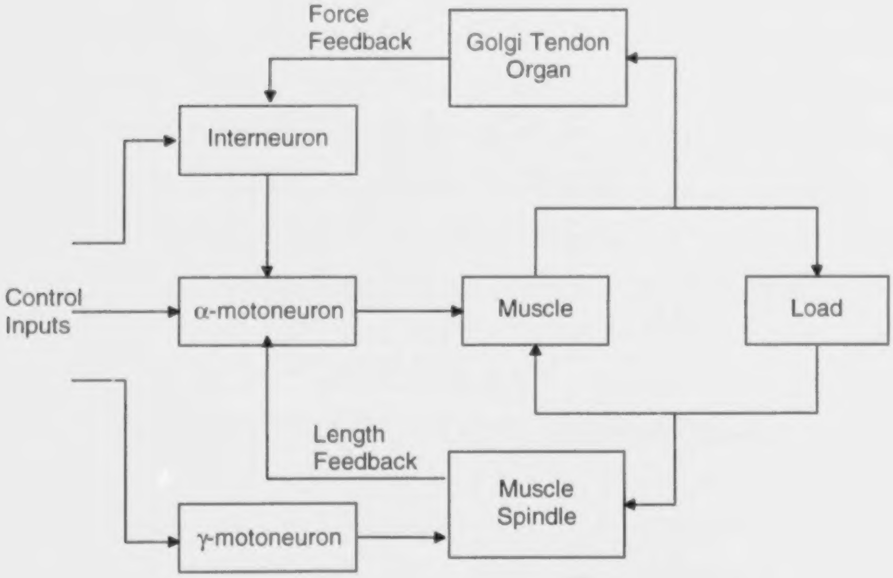
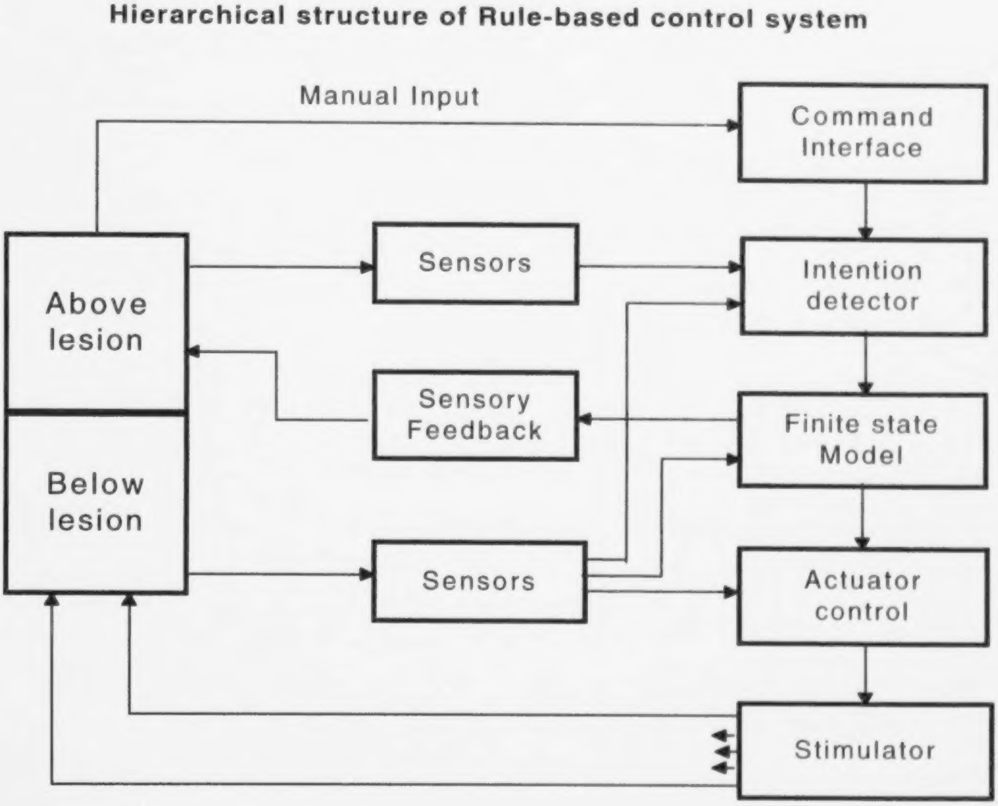

Force Feedback
Golgi Tendon Organ
Interneuron
Control Inputs
α-motoneuron
Muscle
Load
Length Feedback
Muscle Spindle
γ-motoneuron

Figure 1-2. A model of control of movement in mammalian limbs. Control from the CNS is exerted at several points and both length and force feedback are available to modify the motor output (from Stein, 1992).

can cause the performance of an open-loop system to deviate from the preset goal.

From an engineering perspective, the intrinsic non-linearity and variability of muscle output properties suggest a closed-loop control of the FES system in order to gain smooth functional movement and reduce the stimulation amount so as to slow muscle fatigue. In humans, closed-loop or feedback control of motor tasks exists at different levels and the motor control mechanism suggests a hierarchical structure. At the high level, decision is made on both motor intention



Hierarchical structure of Rule-based control system

Manual Input
Command Interface
Above lesion
Sensors
Intention detector
Sensory Feedback
Finite state Model
Below lesion
Sensors
Actuator control
Stimulator

(From Andrews, etal, 1989)

Figure 1-3. Block diagram of the main components in the hierarchical FES control system. This model serves to adapt the strategy at different stages. Sensors are used in both the above and below lesion parts of the man-machine system. They 1) provide direct feedback signals for the low level control, 2) provide signals for state and intention detection , 3) interface the volitional command, and 4) mediate and sensory input. At the low level they are expressed as spinal reflexes to ensure smooth movement of the limbs and fast responses to external disturbances. The richness of sensors (receptors) in human limbs allows flexible control of different variables during different motor tasks, as summarized by Stein in Figure 1-2 [77]. Similarly, the closed-loop control of FES depends upon sensory feedback from natural or artificial sensors on limb position, force, contact and change in load etc. [14]. Different closed-loop control algorithms have been incorporated into the FES systems, including those involving the regulation of muscle stimulation for specific joint movement (low-level control), as well as those coordinating the walking processes [11]. Low-level control has adopted both linear PID (continuous or discrete) or nonlinear feedback control method [10,19,60] and event driven finite state control method termed as artificial reflex [3,53,87].

The continuous control requires sensors to provide fast and accurate output to monitor the limb movement, muscle force and external disturbance etc., which are highly difficult tasks for the sensors. Finite state control, which is also called rule-based control, can be expressed as a set of IF-THEN rules. If a particular sensory pattern is detected during a specified state of the system, then a corresponding motor action or movement is initiated. Sensors in this scheme may be used to sense only discrete and non-numerical events, for which speed and reliability may be the only highest priority. The foot drop stimulator described by Liberson is a simple configuration of rule-based control with one sensor (heelswitch) and two states (stance and swing). In comparison of natural and artificial control mechanisms, Prochazka suggested that rule-based control resembles the natural way nervous systems control the cyclical gait task in many species [67]. Rule-based FES systems have been tested on animal models, and implemented into hybrid systems for paraplegic standing and walking [6,53,64,81,88]. In general, the rule-based control is considered to have a hierarchical structure, as suggested in **Figure 1-3** for a lower extremity FES system by Andrews, et al [3]. In this structure, different closed or open-loop control strategies can be incorporated into individual levels. The highest level is the volitional control of the subject. Gait can be initially started by the subject through command interface such as hand switch, voices etc. Each gait mode is controlled with reference to a finite state model. A step may be initiated by detecting voluntary movement of the intact part or the paralyzed extremities that is uniquely associated with the subjects' intention of stepping. Each gait cycle is divided into a number of states determined by detailed gait tasks, while each state is associated with a predetermined low level open- or closed loop control pattern.

Sensors are used at each level for different control purposes. At the finite state control level, state transitions and step intentions are detected by a set of rules based on sensory signals. The rule set, the current state and sensor outputs together determine if it will go to next state and which is the next state. However, this level does not consider explicitly the system dynamics. To achieve smooth stepping, sensors are needed at the actuator control level for a feedback control of the leg or joint movement using either artificial reflexes or PID control methods. If no sensor is used at this level, the stimulation simply operates in an on/off way and an open-loop within the state with preprogrammed stimulation patterns. It is recognized that reliable control and smooth gait is achieved with assignment of fine states and use of more channels of stimulation, while definition of fine states depends again on the availability of more reliable sensors. A 2-sensor and 4-state controller can achieve a better reliability than a single sensor and 2-state one [67]. In the rule based control, states (events) can be detected using sensors positioned at leg segments, around the joints, under the feet, in orthotic devices or on aiding devices such as crutches, canes and walkers. The significance of a sensor depends on the motor task and the rules that govern the control. Production rules can either be “hand-crafted” from recorded data on trial - and - error basis and individual experience, or it can be generated automatically with machine learning techniques such as artificial neural network and inductive learning algorithm [37,40,54]. Machine learning algorithm may also identify the least number of sensors required or the most significant sensor set [1,7]. On the other hand, skill cloning by using the learned automatic skill of a trained subject can also help to optimize the production rules and enhance the significance of sensors of particular interest [1].

Sensors may also be used to feed back substitute sensory information about the paralyzed part to above the level of sensory lesion through certain type of actuators such as lights, tones, and electro-cutaneous stimulation. For complete paraplegic subjects, sensory information such as posture status is also important for a safe gait. Otherwise, situations may arise where the subject, not being fully aware of his posture due to loss of sensation from the lower limbs, may initiate a gait while his posture is inadequate and thus leading to loss of balance and fall [3,14,24].

1.3 Sensor specifications for FES control

In the sensor aspect, there are two feedback methods. The first method uses artificial sensory feedback from mostly mechanical sensors [14,94]. The second approach is based on natural sensors, using signals from such as EMG and ENG [24,27,30,34,72]. In terms of sensor output, two main categories of sensors involved in closed-loop control have been force displacement sensors. Force sensors can be used to detect force (e.g. , ground reaction force, muscle force, and slip force), pressure (e.g. crutch, foot and sole pressure) and contact information. Displacement sensors in a broad definition include a variety of sensor types that detect joint angle, limb position and balance, etc.. On the other hand, what actually matters is not just the output of sensors, but their overall properties. The efficacy of a closed-loop control depends on the quality of available sensors. Major criteria of a 'proper' sensor includes the type of message it detects, the ease of application to the subjects and the reliability and stability over the time and conditions of use. Crago et al listed the main specifications for sensors used in FES systems for different tasks [14]. For restoring lower extremity functions, the useful signals on the list include the hip, knee and ankle joint angles, foot contact signal, foot pressure and the pressure loaded on the walking aids. There exists an interaction between the type of controller used and the sensors suitable to go with it, i.e., sensor selection depends on the application. Petrofsky et al, for example, used pairs of hip, knee, and ankle goniometers, heel and toe switches, and gyroscopic balance control to realize a finite state and stepwise continuous closed loop control for a complete FES mediated paraplegic gait [60]. Andrews et al used hip angle, insole pressure, walking aid force and the ground reaction force sensors to realize free knee standing and walking of paraplegic subjects in a hybrid system [6]. For some stroke and hemiplegic subjects who preserve sufficient voluntary ability and sensory feedback, a heel sensor or a heel-toe sensor set might be adequate to help improving their gait. On the other hand, the advancement of technology is making it possible to use more suitable sensors or new variables such as limb acceleration, muscle fatigue etc..

1.4 Recent development and implementation of sensors for FES

1.4.1 Artificial sensors

In the *force sensor* category, a lower extremity system often needs sensors to measure the foot contact, foot pressure, crutch loading and ground reaction force etc., as feedback signals. Measurement of foot pressure for gait analysis purposes is usually done with pressure sensitive insoles instrumented with a great number of pressure sensors of stain gauge, capacitance or conductive polymer type [23,29,55,70]. For purposes of feedback control, simpler but more robust and reliable solutions are sought to get the pressure characteristics rather than the accurate pressure distribution. Chizeck et al used four capacitive pressure transducers in a foot insole to obtain the center-of-pressure information on each foot for a closed-loop controller [14]. Veltink et al used crutch loading force sensors together with hip goniometers to identify gait states for a hybrid system using only supervisory control [18]. A vigorous example of using force sensor in a closed-loop control is the floor-reaction-orthosis (FRO) described by Andrews and Baxendale [4]. In this artificial reflex arc [87], a force sensor mounted in the front of a rigid below knee orthosis was used to detect the direction of the ground reaction force vector when the subject is standing. If the sensor output drops below a threshold, indicating the GRF vector moves behind the knee, maximum stimulation is given to the quadriceps to keep the knee locked. However, the most common application of pressure sensors is as a footswitch to detect the heel contact.

Pressure sensors based on conductive polymer materials, especially the *Force Sensing Resistors (FSR)* by Interlink Electronics Inc., USA, have received much attention in recent works on the low extremity FES systems. FSRs are polymer thick film devices which exhibit a decreasing resistance with increasing force (pressure) applied to their surface. They have a logarithmic pressure - resistance output relation. Comparatively, FSR are flexible, inexpensive, durable and easy to fit. Andrews, et al (1989) used four square FSRs to detect the foot contact and limb loading information [6] which was the first published work using FSRs in a FES system. FSRs have been successfully used as foot switches or pressure sensors in FES control [40,78,96], gait analysis [23,96] and measuring the muscle force [75]. The key characteristics also make them very suitable for an insole transducer to detect the temporal parameters of the gait [29]. We used four sensors for each foot insole, as shown in Figure 4-2, in order to locate the most significant sensing point during the gait analysis trials.

Functional gait objectives are mainly stated in terms of kinematics quantities such as angle, position, velocity and acceleration. *Kinematic sensors* are therefore very important in realizing a closed-loop control scheme. Petrofsky et al used externally mounted potentiometers to monitor hip, knee and ankle angles[58]. Recently, flexible *electrogoniometers* have been popular in the FES systems to feed back the joint angles and derive velocity signals in both PID and finite state controllers[19,39,53]. For an FES system used in daily life, however, these externally mounted goniometers are too bulky, subject to slippage of mountings and not robust (need to be recalibrated on daily basis). These disadvantages would be avoided if the goniometer can be implanted at the joints. The potential candidate are *magnetic sensors* operating on Hall effect. An implantable Hall effect goniometer to measure knee angles has recently been proposed [95], but implementation in an FES system has not been published. Bowker et al [9] recently demonstrated a magneto inductive transducer designed to control a peroneal stimulator by monitoring the angular velocity of the knee joint. It consists of a diametrically magnetized disc attached to over the center of the rotation and an induction coil 100 mm away on the leg to pick up the electromagnetic field. This design avoids some of the shortcoming of the electrogoniometer. As a footswitch the positioning of the sensor is still sensitive. Implantation of the sensor was not mentioned.

Accelerometers are another type of kinematic sensors that can be used to measure joint angles, angular velocity and acceleration. As the advancement of semiconductor and micromachining technology, integrated or solid-state accelerometers are available for possible implementation in controlling FES. Willemsen et al (1990) used three pairs of one-dimensional micro-machined accelerometers attached to the upper and lower legs to measure the knee angle in real time [99]., They were also able to detect the equivalent angular acceleration of the ankle joint by using two accelerometers attached to the lower leg alone [98]. With the ankle acceleration signal and a cross-correlation algorithm, they successfully identified the stance - swing gait phases of hemiplegic subjects. This provided a potentially implantable footswitch for peroneal stimulator. Veltink et al (1993) suggested to replacing the knee goniometer by using the difference between signals from two accelerometers attached on the upper leg to detect knee buckling during standing [89] and more recently by using lowpass filtering of accelerometer signal to detect the tilt of both legs during paraplegic gait [89]. The attractiveness of these sensors is that they are integrated one piece units, insensitive to positioning, and no need for daily calibration. Although accelerometers need relatively complex interfacing circuitry and signal processing technique, with the progress of semiconductor technology, they will become more attractive as an implantable artificial sensor in FES application. The main question, however, is left to be further studied: how reliable is the acceleration signal in detecting the joint and gait states in the existence of internal and external disturbances, such as leg spasticity and clonus, stimulation, and use of mechanical braces or walking aid devices?

Sensor signals in a neural prosthesis may be considered as windows to the patient's neuro-musculo-skeletal system in which inadequate motion is being assisted by FES. Each individual sensor is limited in what it can sense and the information it can provide. In other words, the whole neuro-musculo-skeletal status information is decomposed into its components by the sensors. A single type of sensor may therefore probably not be adequate for a comprehensive feedback control strategy. This information fragmentation can, however, be partially reconstructed by a *sensor fusion* process to improve the closed-loop control of the FES- neuro-musculo-skeletal system [7]. Andrews et al proposed a sensor fusion scheme of using machine learning to map a suite of sensors to a comprehensive set of biomechanical variables required for control of a hybrid paraplegic FES system [7]. The multi-sensor suite was composed of 10 dc-responsive accelerometers for detecting inclination and inertial motion, 2 strain gauges for brace loading, and 6 eletro-magnetic position-angular sensors for relative angle and position. They acted as virtual sensors in such a way to monitor some specific variables, such as knee angle during sitting-down and standing-up, forward velocity of the foot during walking, and incipient knee-buckling message during standing, without requiring calibrated sensors such as goniometers.

In simple FES systems such as peroneal stimulators, a robust, reliable and simple-to-use non-invasive external stimulator is no less attractive to FES candidates than an implantable system. Some efforts have been made in using a wireless solution for sensors and switches to mediate the feedback and control information via telemetry method [17,48]. In an effort to seek a wireless and robust sensor replacing the footswitch used by most current peroneal stimulators, we explore in Chapter 3 the integration of another alternative angular sensor, the inclinometer, or *tilt sensor*, into an peroneal FES device for correcting the foot drop. A tilt sensor detects the deviation of the sensing axis from the gravitational vector. It has been used in the navigational systems in aerospace and marine industry. In the FES field, a number of investigators have considered tilt sensors to control posture and body balance of paraplegic subjects [5,59] and as a trigger source of stimulation [13,86], but a comprehensive analysis in the sensor property with FES has not been seen. An inertia tilt sensor is equivalent to an accelerometer having a dc bandwidth. However in most situations a tilt sensor needs a much simpler interfacing circuitry than that for an accelerometer. Miniature tilt sensors are also integrated in size and easy to mount on limb segments. In our study, a finite state approach allows a tilt sensor attached on the shank to effectively detect the step intention and the lower leg position in a population of stroke and incomplete SCI subjects and to synchronize the stimulation. This study has lead to the development of a miniature external peroneal stimulator with a tilt sensor built into it so that the external sensor cable is eliminated without requiring implantation.

1.4.2 Nerve recording technique to use natural sensors

Despite the many efforts, artificial sensors are probably inadequate for nature-like closed-loop control of FES because they still have problems such as reliability, positioning and mounting that prevent them from coping with the clinical environment. On the other hand, the sensory system of the human body itself has various types of natural sensors to relay different environmental information (stimuli). The richness of sensors and the richness of information from the sensor signals are unmatched by any artificial sensor achievable. For example, the rapidly adapting and the slowly adapting mechanoreceptors found in the glabrous skin mediate tactile information; joint receptors and muscle spindle receptors sense the muscle force and limb proprioception. These receptors send their information to the central nervous system through afferent nerves fibers. We may therefore think that the peripheral receptors and afferent nerve fibers together form the natural sensors. Natural sensors present an attractive alternative to artificial sensors for FES control because they provide all the information necessary and are available and function in most of the subjects who are candidates of using FES prosthesis. In FES application, both myoelectric (EMG) signals and neuroelectric signals (ENG) have been used as natural sensor signals for control purposes [24,27,30,31,49,72]. The use of nerve recording for control of human assistive devices was more than twenty years ago [79]. It was first suggested for control of human amputee. Research in animal models with electrodes implanted on peripheral nerves has shown that they could provide long term stable sensory signals suitable for feedback control of FES.

1.4.2.1 Techniques for peripheral nerve recording

The technological challenge of using natural sensors for control of a neural prosthesis comes from two aspects: to record stable sensory signals from the afferent fibers in the long term, and to extract useful information from the signals in real time. Three main techniques have evolved for long-term recording of peripheral nerve activity in free-moving animals: intrafascicular microelectrodes for recording the activity of individual neurons, multifasicular intraneuronal electrodes for recording the activity of a group of neurons simultaneously, and nerve cuff electrodes for recording the whole-nerve activity [30].

Single unit intrafascicular recording from unrestrained subjects is normally achieved with floating microelectrodes that consist of a short stiff needle wire attached to a compliant lead-out wire that is kept in close proximity to the axon to pick up the extracellular potential of the neuron. This type of recording can only be made from mechanically constrained nerve trunks such as dorsal or ventral roots. Because of migration, breakage and encapsulation problems, single neuron intrafascicular electrodes remain in the research domain. Electrodes implanted in dorsal or ventral roots of cats can provide stable recordings from the same axon for several hours to several days. It is therefore useful to study neuronal sensory and motor activity in conscious animals. To be clinically applicable, however, the functional lifetime of floating microelectrodes must be improved substantially. On the other hand, recordings from a single axon is not suitable for feedback control because they are prone to large variations [30,34].

Multiunit intrafascicular recording involves flexible monofilament wire electrodes inserted in individual nerve fascicles to record the activity of small subpopulations of axons. In University of Utah, chronically implanted bipolar intrafascicular electrodes made of carbon fibers have recorded unit fiber activity from peripheral nerves for periods in excess of six months [44]. Multiunit intrafascicular recordings could monitor several different modalities and sensory fields simultaneously, which is a very demanding feature for controlling fine movement such as hand grasping where spatial details are needed from the sensory information. However, the microstructure of a sensory nerve presumably varies along the course of nerve fibers with unknown patterns. Therefore the electrode implantation is not robust and real-time signal recognition becomes very difficult [51]. On the other hand, multiunit intraneuronal electrodes suffer similar mechanical limitation as those for single unit recordings, such as drifting, breakage and encapsulation that make the electrode functional lifetime limited. Better electrode materials and more advanced signal recognition technique must be sought before they become clinically applicable [52].

Nerve cuff electrodes for chronic neural recording, with conductive wires placed around an mylinated nerve trunk, were first proposed by Hoffer and Stein et al, 20 years ago, although the practice of using cuff electrodes to deliver electrical stimulation to human nerves has been around for a longer time [30,79]. Research in animals with chronically implanted tripolar cuff electrodes showed that they could be used successfully for long periods. After initial changes in electrical properties of electrodes during the first weeks following implantation, recording from chronically implanted cats showed that the electrode impedance, peak-to-peak amplitude and latency of the nerve potential were stable for periods over 3 years [20,80] [Chapter 2]. Historical studies found no serous nerve damage during long term recording with a nerve cuff if it is constructed and implanted properly. The neural activity recorded with cuff electrodes normally contains mixed signals of both aggregate sensory and motor information that is difficult to interpret. However, for the very peripheral cutaneous nerves, adequate sensory information can be extracted from the nerve cuff recordings with relatively simple signal processing. Using a nerve blocking cuff distal to the recording cuff, Hoffer et al demonstrated that the signal recorded from tibial nerve cuffs on the cat hindlimb was indeed produced by tibial nerve afferent fibers [30]. Chronic recordings from the human sural nerve in a hemiplegic subject by Sinkjaer et al and semi-chronic recordings from the palmer digital nerve in hand injury subjects by Popovic et al confirmed that nerve cuff electrodes could be used to record sensory nerve activity during walking or grasping. [66,72,74]. Nerve cuff signals feature considerable spatial and temporal averaging and are therefore far smoother and less sensitive to the specific location and detailed pattern of the skin input than signals recorded from individual mechanoreceptors. This property of cuff signals could be very desirable for feedback regulation of an FES controller. In the aspect of clinical implementation, nerve cuffs are mechanically stable and robust. The long term safety and stable performance in human is witnessed by the use of nerve cuff as stimulation electrodes. To date, nerve cuff electrodes, based on the simple concept, appear to be the only possible clinically feasible candidate to extract natural sensory feedback signals in humans or animals.

1.4.2.2 Using nerve cuff electrodes in closed loop control of FES for hand grasping

Restoration of function by FES in the upper extremity has focused principally upon hand grasp-release. Consideration has been given to the type of grasp, the necessary forces to achieve, and the precision of control [57]. In able-bodied individuals, successfully lifting, holding, or releasing an object with a hand requires a refined coordination of forces exerted on the object by tips of the fingers and thumb. These simple acts involve both preprogrammed and continuous feedback control of the grip force by the muscle-nerve system [32]. For example, when lifting an object, the balance between the grip force and the load force is quickly adapted to the frictional condition between the skin and the object. Unexpected external perturbation on the object load when holding the object would evoke automatic and graded increases in the grip force that prevent slip of the object. Studies by Johnsson et al have shown that the tactile afferent, mainly the FA I, SA I & II cutaneous sensors, excite on the change of the grip condition of the hand-object interface and are responsible for the "grasp reflex arc" that ensures smooth and accurate grasp [32,33,46]. Practical FES-controlled grasping systems, either EMG controlled or artificial sensor controlled, such as the Edmonton Grove, have been developed, mostly without a feedback regulation of the stimulation during the grasping [49,71,97]. They have been providing adequate functions for the basic grasping tasks in certain populations of quadriplegic subjects. Similarly, control of slip during grasp would be an important add-on advantage to SCI subjects who use a FES system because otherwise with an open-loop FES controller they would generally require sustained high level muscle contraction to ensure adequate grip and are therefore subject to early muscle fatigue and soft tissue stretch problems. However, it is difficult for artificial sensors to relay the necessary information such as slip at the finger tips and still difficult to mount in the hand grasp FES systems [14,15,94]. As implantable FES systems have become available, the need for implantable sensors also becomes apparent [57]. Use of natural sensor signals in a hand grasp controller would be as attractive as an reliable implanted artificial sensor. As have been shown, nerve cuff electrodes present major advantages over intrafascicular electrodes in providing viable long-term recording. Hoffer et al correlated the whole nerve activity recorded from tibial nerve with external cutaneous inputs, including slip and perpendicular touch, to the central footpad of the cat hindlimb which served as a model of glabrous skin in human fingertips [30]. They further implemented an "artificial gripping reflex" for paralyzed hand gripping and lifting using the real-time slip information extracted from the recordings [27]. In the cat model, FES was applied to the ankle plantarflexor muscles to cause the footpad to press against and grip an object. The neural activity recorded with a cuff electrode implanted on the tibial nerve was used by an event-driven controller that allows the FES to compensate for slips caused by either muscle fatigue or external perturbation in a simple threshold detection method. A practical FES grasp controller for a paralyzed human, on the other hand, needs to control various grasp related functions, such as lifting, holding, moving and releasing an object, during which an increase in the whole nerve activity may not necessary mean a need for increase of grip force. Based on the findings from nerve cuff recordings in humans [72], a possible scheme for a slip-based grasp controller that uses cutaneous sensory feedback could mimic the elegant natural control scheme used by the able-bodied hand [34]. However, demonstration of such a system will have to first solve difficulties such as discrimination of slip information from transient events other than intended increases in force.

1.4.2.3 Using nerve cuff electrodes in closed loop control of FES gait

Theoretically, the fact that gait is cyclic and largely predictable makes the use of natural sensors in gait more robust than in grasp. On the other hand, in lower extremity FES systems more relevant artificial sensors are available and less sensor mounting problems than in the hand-grasping systems. Use of natural sensors therefore needs to present clear advantages over artificial sensors to be practical. The study conducted by Hoffer and collaborators showed that it is possible to extract reliable information that represents activity of cutaneous, muscle and joint afferents from whole nerve recordings [27,28,30]. In Chapter 2, we describe a method demonstrating the integration of recordings from multiple chronically implanted nerve cuffs in cats in a closed-loop control scheme to restore locomotion with FES. In the study, whole nerve recordings from tibial and superficial peroneal nerves are used to detect the instants in real time when ankle flexor (m. tibialis anterior) and extensor (m. medial gastrocnemius) should be turned on and off. Improved instrumentation technique is used to derive artifact free nerve recordings in the presence of stimulation [26]. After filtered out the EMG contamination, the rectified and integrated ENG signals present close correlation with the primary gait events and thus flexor/extensor contractions. Using threshold detection, we are able to derive the states of gait for a simple rule-based control scheme. For comparison, An adaptive neural network is also used to determine the gait invariants to be used for closed loop control schemes.

More recently, Sinkjaer et al started to examine the clinical application of nerve recording from cuff electrodes [72,73]. They implanted a nerve cuff electrode in a hemiplegic subject who suffered a stroke and who was a candidate for a single channel FES system. The system was designed to synchronize the stimulation with the swing phase during walking and improve ground clearance of the affected leg by stimulating the peroneal nerve and triggering a flexion reflex. The cuff electrode on the sural nerve serves as a foot switch to detect ground contact. The sural nerve carries information from cutaneous receptors from the lateral side of the foot and hence every time the foot touches the ground an increased neural activity can be detected. (In the cat, we found that the sural nerve is very thin and close to the moving skin, so that the cuff signals recorded are very weak and subject to strong EMG contamination). The electrode provides reliable triggering signals even when the subject is wearing his socks or shoes. This system has distinct advantages over other single channel stimulation devices in that it can be completely implanted, eliminating the cables and daily sensor mounting effort. The success of this test suggests that nerve cuff electrodes may provide a good solution to sensor needs.

1.5 Objective of the thesis study

Natural and artificial sensors can be used to improve FES control of walking. In rule-based control, the requirements for feedback sensors include high reliability and good stability in a daily living environment, robustness, and superior mechanical properties such as small size, ease of use and good cosmesis. The purpose of this thesis study is to investigate the chronic nerve cuff recording method as a technique of using natural sensors and tilt sensors as a robust alternative to footswitches for rule-based FES control of walking. The general objective is to find sensors suitable for closed-loop control of FES assisted walking.

1.6 Sensors applied in the research project

Two efforts are made in this study attempting to locate proper sensors facilitating the control of FES. In chapter 2, we study the possibility of using the intact sensory nerves as the natural sensor by recording the sensory signals of cats with nerve cuff electrodes implanted in the hindlimbs. In chapter 3, tilt sensors are studied for their application in FES as a replacement of the footswitch. The studies are aimed at the same direction as to improve the robustness, cosmesis and the reliability of simple FES systems suitable for the daily practical use.

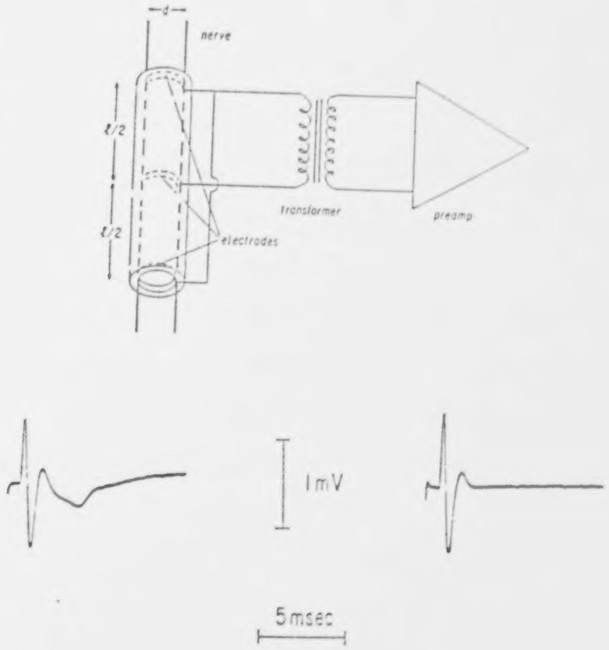
1.6.1 Tripolar nerve cuff electrodes

The sensors used to record from the sensory nerves are cuff electrodes. The nerve cuff electrodes consist of metal electrode wires sewn into Silastic tubes to be placed around nerves. In this way, the sensor records the compound action potentials of the whole nerve.

The Silastic cuff tubes are varied in internal diameters from 1.0 to 3.4 mm and in length from 1.5 to 5 cm, customized for the size of the particular nerve for recording. The tube is slit longitudinally in order for the nerve trunk, which is normally 1.0 to 1.7 times thinner in diameter, to be inserted inside [30,82].

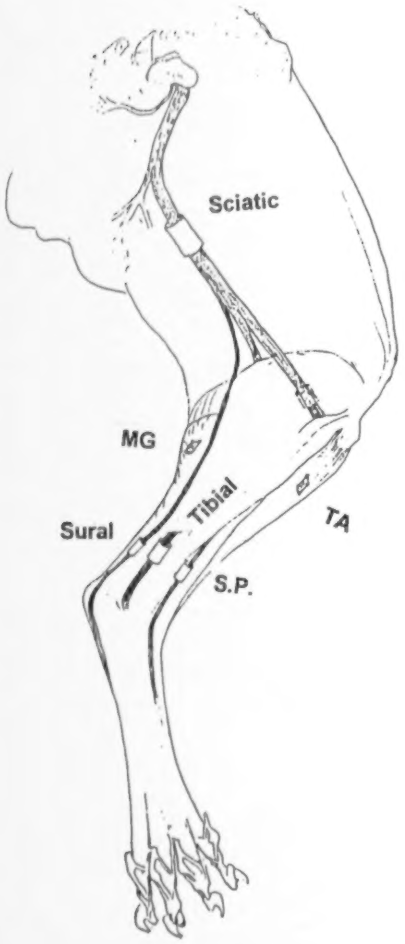
The metal electrodes are made from Teflon coated multi-stranded stainless steel wires which have been used for implanted intramuscular stimulation electrodes by Dr. Prochazka [69]. They have the advantage of low electrical impedance, high tensile strength and good corrosion resistivity as stimulation electrodes [12]. The wires, after their tips stripped, are sewn into the Silastic tubes in three 90° arcs forming a conductor ring internally around about 270° of the circumference of the cuff. Two or more coats of medical grade Silastic are then applied to the outside of the cuff to insulate the wires. In this way, the small action currents generated by the nerve fibers are constrained to flow within the long and narrow resistive path and the large EMG potentials generated by nearby muscles as well as signals generated by any other sources outside the cuff are greatly attenuated by the internal electrodes. Wires are also sewn into the outside surface of the cuff lengthwise to serve as external ground electrodes because they are exposed to fluids. For best rejection of EMG contamination, a balanced tripolar cuff is formed using three of such electrodes for differential recording as shown in Figure 1-4.

Figure 1-4. Tripolar nerve cuff electrode: a) in the configuration, the electrodes at the 2 ends are shorted together, the middle electrode as the indifferent terminal; b). the compound action potential picked up by a tripolar cuff shows triphasic property.



In this symmetrical configuration, recording is made from the two electrodes at the ends of the cuff that are shorted together and the center electrode is the indifferent. In this way the EMG current leaked from outside in the cuff direction is shunted while the neural signal flowing in the nerve trunk is picked up as a triphasic signal instead of biphasic, as shown in Figure 1-4b. The fiber diameter,

Figure 1-5. In the study, cuffs are surgically implanted onto the sciatic, tibial, sural and superficial peroneal nerves of cat's hindlimb for chronic recording. Two patch electrodes are also implanted onto tibial anterior and medial gastrocnemius muscles which are flexor and extensor of the ankle joint to record EMG or deliver the stimulation.



Cuff	Length	Din	Dout
Sciatic	3 cm	0.104"	0.185"
Tibial	2 cm	0.104"	0.185"
Super. p.	2 cm	0.078"	0.125"
Sural	2 cm	0.062"	0.095"

cuff inside diameter, cuff length and the inter electrode distance determine the shape and amplitude of the compound potentials recorded. To obtain maximal signal amplitudes, the distance between the two end electrodes of the tripolar cuff should be close to the wavelength of neural action potentials in the prominent fibers. To avoid compression damage to the nerve, the cuff I.D. should be about 20% larger than the nerve diameter [16,30]. The neural signal properties and underlying principles using the nerve cuff are described in detail in [79].

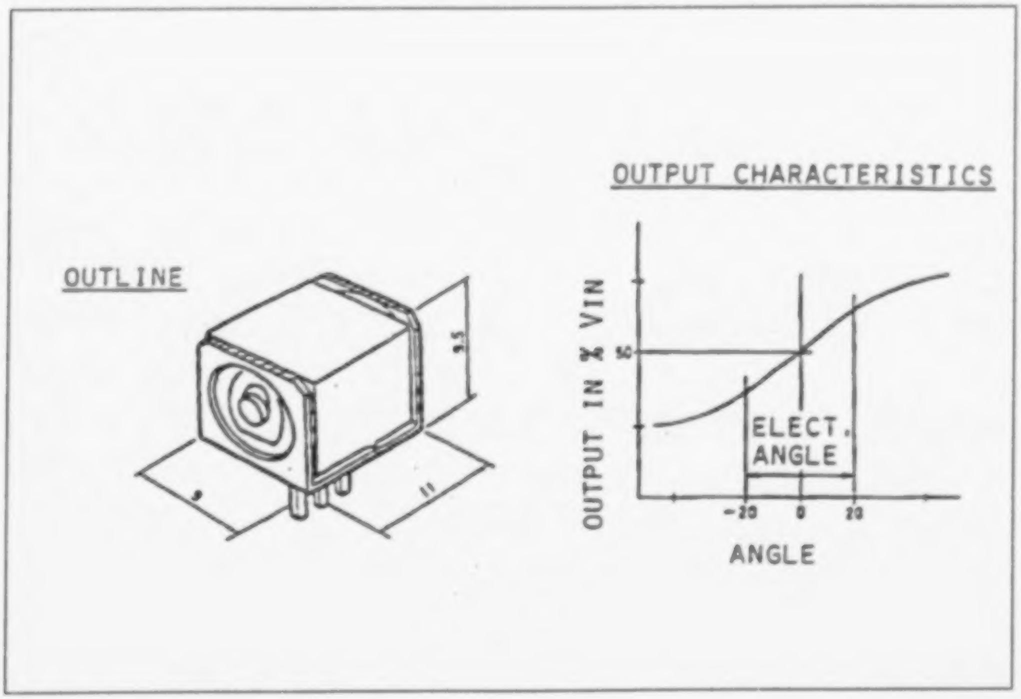
The cuffs are surgically implanted onto the sciatic, tibial, sural and superficial peroneal nerves of the cat's hindlimbs for chronic recording, as shown in . The surgical procedure are described in section 2.2 in detail. The long-term physiological effect of cuff electrodes for recording sensory nerve activity chronically has been proven safe [20]. The electrical properties to identify a cuff electrode have been the electrode impedance, peak-to-peak amplitude and latency of compound action potentials. Preliminary result in chronically-implanted cats shows that these parameters are stable after initial weeks following implantation.

1.6.2 Tilt sensors

A tilt sensor or inclinometer detects the angle between a sensing axis and a reference vector such as gravity or the earth's magnetic field. It therefore has the potential to measure the spatial parameters of the gait. A conventional tilt sensor consists of an inertial element such as a liquid that senses gravity and a signal transforming element. When the body of the sensor tilts, gravity causes a relative movement of the inertial element which is then converted into resistance, capacitance and current changes by different signal transforming techniques. The major problem of an inertial tilt sensor used in a dynamic environment is its response time and its response to accelerations. Non-inertial tilt sensors that use the earth's ambient magnetic field as a reference vector avoid the inertial problem, but some other key specifications of these sensors achieved to date, such as sensor size and current consumption, make them less suitable for FES application.

For FES application the important sensor characteristics include physical size, mechanical reliability, dynamic response, signal stability of the sensor in a daily living environment and the simplicity of conditioning the sensor signal. We tested three different types of commercially available tilt sensors: a miniature electrolytic tilt sensor made by Spectron Glass and Electronics, Inc., two magnetoresistive tilt sensors from Midori American Corp., and a mercury tilt

Figure 1-6. UA-1 miniature tilt sensor. It is a magnetoresistive sensor operates on the Hall effect. When the sensor body tilts in the axial direction, the pending magnet mass moves from its original position and the magnetic field changes. A thin film magnetoresistive chip placed in the middle slot senses the change of the magnetic flux and its resistor changes accordingly



sensor from COMUS International Inc.. Figure 1-6 shows the Midori UA-1 miniature sensor that is used in the WalkAid foot drop stimulator. Analysis of the electrical properties of the tilt sensors concludes that they are suitable for detecting limb movement during gait and possible application for FES control. In chapter 3, we demonstrate that, with lowpass filtering and threshold detection, tilt sensor signals from the shank may be used for detecting the states of the hemiplegic gait.

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2. SENSORY NERVE RECORDING FOR CLOSED-LOOP CONTROL TO RESTORE MOTOR FUNCTIONS 42

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2. SENSORY NERVE RECORDING FOR CLOSED-LOOP CONTROL TO RESTORE MOTOR FUNCTIONS[1]

2.1 Introduction

Technology for functional electrical stimulation (FES) to restore movement in paralyzed limbs has advanced substantially. Implantable electrodes for safe and selective percutaneous stimulation are available [30] and fully implantable systems will be commercially available in the near future [18, 36]. However, adequate control of FES systems remains a major problem. Redundant muscle groups can not be controlled in the same way that the central nervous system (CNS) controls them. In addition, a CNS injury results in modified reflexes (e.g., spasticity), so inappropriate contractions may be produced. Finally, the changed patterns of activity are responsible for modifying the contractile properties of different muscle groups. Overcoming these problems requires closed-loop control with reliable, reproducible sensory feedback. Experience in using artificial sensors has proven to be complex with numerous problems associated with mounting, reproducibility, robustness, energy consumption, etc. [40].

Sensing natural signals to control assistive devices was suggested a number of years ago. For example, myoelectric hands and legs have been designed and used with variable success (reviewed by Graupe and Kohn, [8]). Published results by Johansson and Westling suggest that cutaneous sensory receptors have some appropriate properties for control purposes [15, 41]. Nerve cuff electrodes have proven to be safe and reliable for recording sensory nerve activity chronically in animals and so are a promising source of feedback information [7]. To maximize the amplitudes of the neural signal a nerve cuff should be well matched to the size of the nerve and be approximately as long as the wave length of the action potential. Up to this length the signals increase as the square of the electrode spacing and inversely as the square of the internal diameter of the cuff [10].

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[1] A version of this work was published in IEEE Trans. Biomed. Eng., vol. 40(10), pp. 1024-1031, 1992, Authors: D. B. Popovic, R. B. Stein, K. Jovanovic, R. Dai, A. Kostov. This chapter includes the part of the work involving rule-based control. The cuff electrodes and cats were prepared by Ms. Jovanovic, surgery and main investigators are Dr. R. B. Stein and D. B. Popovic. My contribution to the work included measuring the latencies and amplitudes of the CAP's from the nerves and electrode impedance after implantation, recording the nerve cuff signals from the cats and testing the rule base.

Hoffer and his collaborators correlated neural activity with external perturbations such as touch, slip and change of contact force in experiments in cats and humans [11, 12, 31]. They succeeded in using a biological sensor in a closed-loop control system for control of the cat's hind limb [13]. Semi-chronic recordings from the palmar digital nerves confirmed that a similar correlation can be found in human grasping [28]. In this paper we extend previous studies by using multi-electrode recordings for the design of rule-based control, which we feel is an important element in the development of a fully implantable system for severely handicapped humans (e.g., spinal cord and stroke patients) needing a multi-channel FES system. Some of these results have been presented briefly at recent meetings [17, 29, 35].

2.2 Methods

2.2.1 Surgical procedure

Experiments were performed on adult cats of either sex that showed suitable gait performance on a treadmill after a period of training. Under fully sterile conditions, a gas-sterilized set of electrodes was implanted and a head and/or back connector was attached according to the following protocol approved by a local ethics committee. Prior to surgery the cat was injected intramuscularly with an antibiotic (Ayercillin) to minimize the risk of infection. It was then anaesthetized with 50 mg/kg of Somnitol given intraperitoneally. Regulation of anaesthesia depth was accomplished by regular monitoring of heart rate, respiration rate and the absence of reflexes to noxious stimuli (eye blink and limb withdrawal to paw pinch). Ketamine and atropine were injected intramuscularly and the cat was intubated to allow artificial ventilation, if necessary. During surgery blood pressure and body temperature were monitored, and temperature was maintained with a heating pad. An intravenous catheter was inserted into the cephalic vein for infusing fluids when necessary. The cat was shaved and scrubbed with Betadine in the region of the incision before being draped with sterile sheets. These procedures were carried out by Veterinary Resource personnel.

Triphasic cuff electrodes [33] were implanted around several of the following nerves: sciatic, superficial peroneal (SP), tibial, common peroneal and sural. Epimysial EMG electrodes were sewn to medial gastrocnemius (MG) and tibialis anterior (TA) muscles. After the surgery the skin was closed with sutures and the tracheal tube and venous cannula were removed. When a back connector was used the leads were brought out through the skin and attached to the connector after the surgery. After completing the procedures, the animals were transported to the intensive care unit of the animal care facility. Post-surgical care included one week of antibiotic therapy (Ayercillin), opoid-based analgesia (Buprenorphine) as required, and close supervision by investigators and support stuff in the animal care facilities of the University of Alberta.

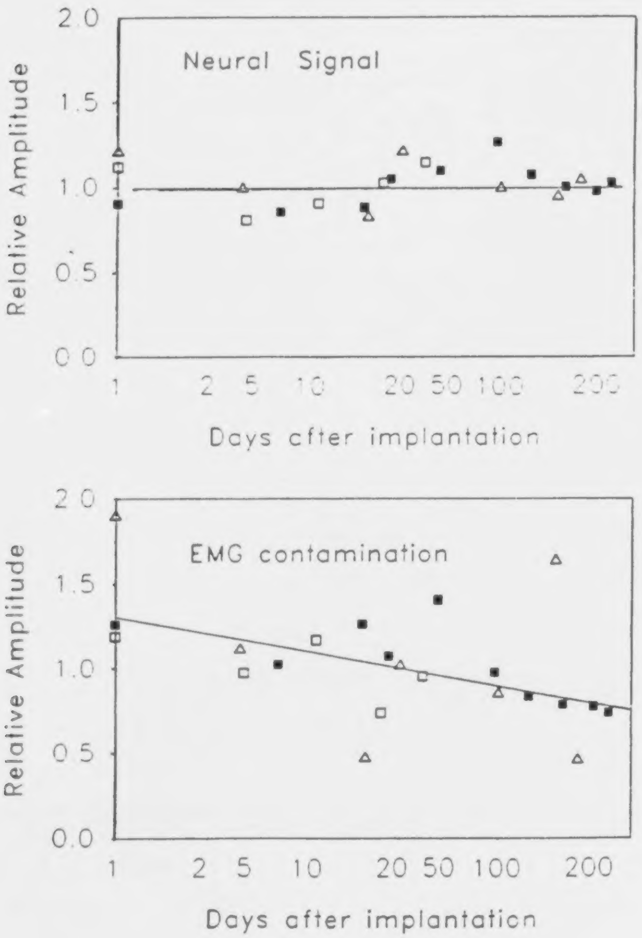
2.2.2 Monitoring.

Compound action potentials (CAP) were elicited by stimulation of nerves at 1 Hz with a pulse width of 10 ms, and an amplitude sufficient to generate a maximal potential. These measurements were done for all implanted electrodes to verify that normal conduction was preserved and no nerve block occurred as a result of surgical intervention. An increase of peak-to-peak amplitude was often observed in the first few weeks after surgery in parallel with an increase in the electrode impedance, due to the replacement of saline with connective tissue of higher impedance [34]. Impedances were measured with a Hewlett-Packard Vector Impedance meter (Model 4800A) at 10 kHz, since the major component at that frequency is thermal resistance. As expected, phase angles at that frequency were typically small ($<30^{\circ}$). No change in conduction velocity was observed, indicating that the nerve diameter had not changed. Neural recordings are stable and with time less EMG contamination is recorded (Figure 2-1). Results from three cats for more than 200 days show that relative amplitude of the peak-to-peak CAP remains constant. In comparison, the relative contamination of CAP by EMG decreased somewhat in all chronic cats.

2.2.3 Signal processing

Neural recordings in peripheral nerves elicited from cutaneous receptor or muscle spindles are typically in the range of 3 to 10 mV. The frequency spectrum has a peak between 2 and 3 kHz with most power concentrated between 1 and 5 kHz. The thermal noise with nerve electrodes is in range of 1 mV, comparable in size with the neural signals. Peripheral nerves are surrounded by muscles producing electrical signals that are orders of magnitude larger, but have a peak near 100 Hz (Figure 2-2, top) and most power below 500 Hz. This signal is partially suppressed using a good fitting cuff electrode and suturing it tightly shut. In addition, the triphasic nature of the recording produces additional common mode rejection [32]. Thus, for the tibial nerve near the ankle, two distinct peaks are observed in the spectrum (Figure 2-2, center) and high pass filtering at 1000 Hz (fourth order Kron-Heit filter, Model 3700) can eliminate virtually all EMG contamination (Figure 2-2, bottom). With other nerves (SP, sural) the location near major muscle groups may require a cutoff frequency of 1500 Hz or more.

Figure 2-1. The amplitudes (top) of compound action potentials were measured with triphasic cuff electrodes on three different nerves (sciatic, tibial and superficial peroneal) in three legs (different symbols) of two chronic cats. The potentials were elicited by stimulating the sciatic nerve and recording from the other two nerves which are branches of it and by stimulating the branches while recording from the sciatic. The four values relative to the mean for each nerve over the entire recording period were averaged and plotted in the Fig. The amplitudes of EMG contamination on the other nerves (bottom) were also averaged in the same way when the sciatic nerve was stimulated maximally. The EMG contamination could easily be distinguished because of its greater latency and slower time course.



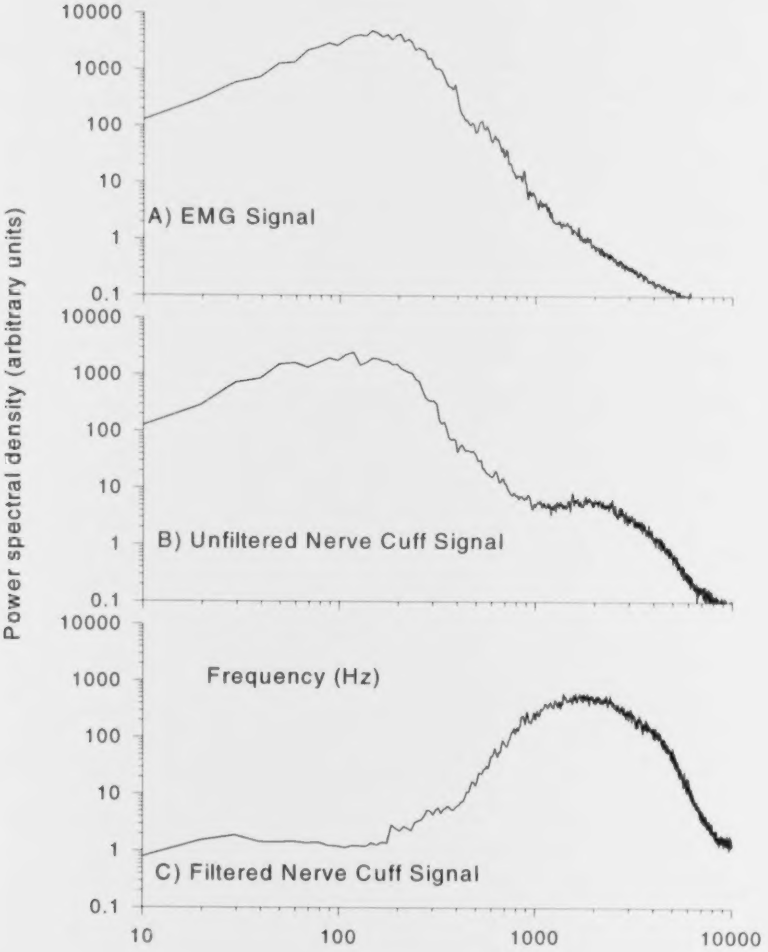


Figure 2-2. Power spectral density calculated from the EMG recorded from medial gastrocnemius (MG) muscle while a chronic cat walked on a treadmill (top). Corresponding spectra are shown from a nerve cuff on the tibial nerve without filtering (center) and after high-pass filtering with a cutoff at 1000 Hz and amplification by a factor of 10. Note that without filtering the peak spectral density of the EMG is 500 times that of the neural signal (over 20 times the amplitude), but the ratio can be reversed using a 4th-order filter.

2.2.4 Circuit design

When stimulating a nerve or muscle, such as would occur in FES, a much larger artifact is produced, which is best eliminated by using a blanking circuit (Hoffer and Haugland, 1992). To measure the average output from the nerve, the signal is rectified and low-pass filtered, using a combination of RC and Paynter filters. Although these techniques have been used for a number of years with rack-mounted equipment, the challenge was to develop a portable system with small-enough size, weight and power consumption that it could be used conveniently in an FES system. To match the low impedance typically observed with nerve cuff electrodes to the high impedance that is suitable for FET preamplifiers, a miniature step-up transformer (turns ratio of 20) was employed (PICO 24400). Total amplification was on the order of 10^5 for EMG signals and 10^6 for nerve signals. The blanking circuit (realized with a 4066 CMOS circuit) switches the amplifier to ground just before and after the stimulation. To prevent the output from decaying, the low-pass filtered signal is sampled and held for the period of the blanking. CMOS technology was used widely to reduce power consumption. The total power consumption is currently on the order of 9.5 mW and the conventional printed circuit boards occupy a volume of 8 cc per channel. Further details can be found in [23, 29].

2.2.5 Rule-based control of FES system

The control architecture system adopted in the present system is based on the finite state approach to the control of prosthetic and orthotic devices. The implementation of the finite state approach is based on the use of a rule-based control. Rule-based control methods belong to non-analytical control systems and have an **if-then** structure [29]. The cyclic motor activity is presented as a sequence of discrete events. Each of these discrete events is associated with a unique sensory pattern. A sensory pattern occurring during particular motor activity is recognized with the use of artificial and/or natural sensors. The specific discrete event is called the state of the system by analogy to the state of finite-state automata. A recognized sensory pattern during a specified state of the system initiates corresponding functional movement.

Rules in a rule-based control system were initially hand-crafted. This involved human expertise and it was very appropriate for simple systems having a limited number of states. The expertise for detecting the rules can be classified as a pattern recognition problem. An alternative to hand-crafting event detection rules is to use rule induction methods, developed for machine learning in artificial intelligence [3,39]. The following steps are included in this method: 1)collection of examples, termed the training sets; 2)each example in the training set is described in terms of a fixed number of attributes; 3) each instance in the training set has an associated class value; and 4) the algorithm seeks to characterize each class value in terms of its attribute values. The development of artificial neural networks gives a new tool for computer generation of rules for control of an assistive device. However, in this part of the work, the used rule number is small enough to be hand-crafted.

2.3 Results

We concentrated in this study on controlling a single joint by stimulating ankle extensors and flexors and processing signals using custom-build electronic circuits (see Methods). Figure 2-3 shows typical records from the SP and tibial nerves as well as ankle extensor (MG) and flexor (TA) muscles of a chronic cat implanted previously. The signals cover a period of 20 s, where the cat stood for 3 s, made one step, stood again for about 2 s, climbed up on the wall of the treadmill with its forepaws while balancing on its hindlegs (note the strong burst of activity recorded in the MG muscle), took another step and then stood for 2 s before starting to walk rhythmically on the treadmill with a cycle time of T » 750 ms. There is a characteristic double burst with each step in the SP nerve and a single burst in the tibial nerve. Furthermore, although the signal amplitudes are much smaller, the processed electroneurograms (ENG) are much more reproducible in amplitude from step to step than the corresponding EMG signals.

The ENG signals were also used to design a simple state diagram, based on setting thresholds on the filtered nerve records (dashed lines on Figure 2-4). The single peak in tibial nerve activity occurs each time the cat's paw hits the ground and corresponds closely to the time when the MG activity begins. Thus, the first rule in Figure 2-4 is: **if** the tibial nerve signal exceeds threshold, **then** activate the MG stimulus for a period corresponding to the average duration (307 ms) that the MG activity remains above a threshold level (not shown). As mentioned above,

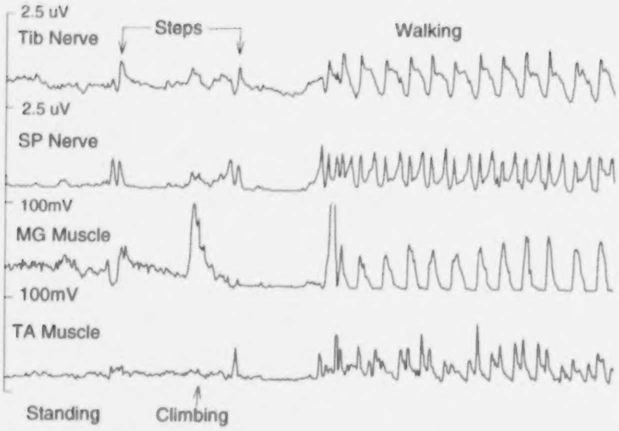


Figure 2-3. Recordings from superficial peroneal (SP) and tibial nerves as well as MG and tibialis anterior (TA) muscles of a chronic cat. This 20 s record was selected to indicate the distinct rhythmic activity in peripheral nerves and ankle muscles during various behaviors. Further details in the text.

the SP nerve shows two peaks, one corresponding to the time when the paw hits the ground and another, larger peak when the paw is lifted off the ground. The latter peak corresponds to the onset of the TA activity. Thus the second rule is: **if** the SP activity exceeds its threshold **and** the tibial nerve is below its threshold, **then** activate the TA stimulus for a period equal to the average duration (420 ms) that the TA activity remains above a threshold level. These two simple rules are sufficient to reproduce the basic structure of the alternation between the flexors and extensors controlling the cat's ankle joint.

In the example shown in Figure 2-4 no stimuli were actually applied. However, with the blanking circuit it was possible to stimulate the muscle to generate substantial force without affecting the sensory nerve recordings. This is shown in Figure 2-5 for the tibial nerve. Hoffer et al. [12] obtained similar results, but used a computer to process the signals. A number of years ago Hoshimiya et al. [14] developed an analog circuit for this purpose. The results shown here utilized a smaller, more modern, battery operated circuit (see Methods) that a patient could use practically on a daily basis.

2.4 Discussion

Up to the present only simple control algorithms have been applied to FES systems for restoring gait, such as hand switches to initiate each step or preprogrammed sequences. These sequences are based on recorded average EMG patterns in normal individuals [19, 20, 21, 37]. Direct, computer control of electrical stimulation was proposed [5], emphasizing muscular properties and a discrete model for restoring functional locomotion. The use of feedback can improve the performance of FES systems. One approach relies on sensing natural signals (e.g., EMG activity) for control [8], while another uses artificial sensory feedback [6]. A few closed-loop systems relying on rule-based control have been tested with artificial sensors by a number of investigators [1, 2, 3, 16, 22, 24, 25, 26, 27, 39].

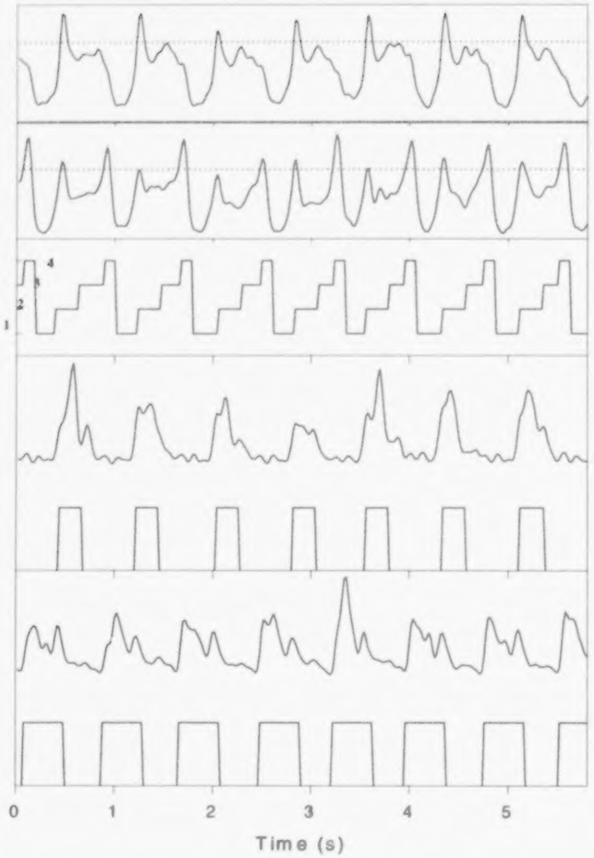


Figure 2-4. Threshold levels were set (dashed lines) to determine instants when processed electroneurograms (ENG) from the tibial and SP nerves (upper traces) crossed above these preset values. Threshold crossings activated transitions in a simple rule-base with four states (third trace), as explained further in the text. Entering state 2 turned on circuits for a fixed period of stimulation (trace 5) that corresponded on average to the duration of suprathreshold activity in the MG EMG (trace 4). Similarly, entering state 4 turned on a circuit for a period (bottom trace) corresponding to the suprathreshold period of the TA EMG (trace 6). Note that the circuit operated reliably with no false positives or negatives.

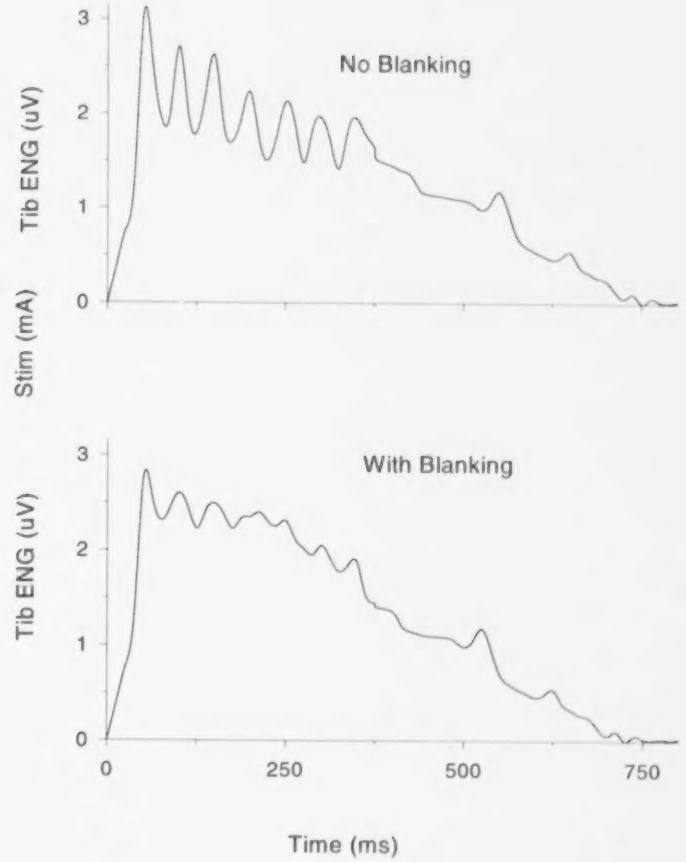


Figure 2-5. When the rule-base was connected to a stimulator and stimuli were applied (middle trace), artifacts were generated on the processed tibial ENG (top trace), even with filtering, but these could be greatly reduced (bottom trace) by switching in a blanking circuit.

To prove the hypothesis that multi-electrode recordings from sensory nerves can provide satisfactory information for rule-based control, we used a chronic cat model. The ankle joint of the cat's hind limb was selected for several reasons: 1) many characteristics of peripheral nerve recordings and muscle signals are well described in literature; 2) a percutaneous system consisting of several nerve-cuff and epimysial recording electrodes can be easily installed; 3) cats can be trained to perform simple motor tasks, such as walking on a powered treadmill and 4) long term recording and stimulation has proven to be effective. In this model system recordings from two sensory nerves (tibial and SP) were sufficient to trigger the appropriate periods of stimulation reliably to ankle flexor and extensor muscles. The rule-base of Figure 2-4 only matches two features of the normal EMG signals, their onset and average duration, but it does so reliably (no false positives or false negatives). It may be desirable for some purposes to match the exact timing for each step. Therefore the same model was tested with an adaptive logic networks (ALN) [4]. The exact timing of activity could be learned using an ALN (details in Kostov [17]). It responded reasonably well to testing with a distinct data set, but it remains to be seen how widely the ALN can generalize and how reliable it would be in a patient application. Until these questions are resolved, the simpler rule-bases operating from artificial or natural sensors seem to offer the most promise for patient application in the near future.

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3. APPLICATION OF TILT SENSORS IN FUNCTIONAL ELECTRICAL STIMULATION[1]

3.1 Introduction

A tilt sensor or inclinometer detects the angle between a sensing axis and a reference vector such as gravity or the earth s magnetic field. It has been used in various industrial areas related to aerospace, automobiles and entertainment. In the health sciences tilt sensors have mainly been used in occupational medicine research[7, 12, 17]. For example, Otun and Anderson used an opto-electronic tilt sensor to continuously measure the sagittal movement of the lumbar spine [12]. Application of tilt sensors in gait analysis is also under investigation [15]. Potentially, tilt sensors have applications for improving the function of persons with motor disabilities. Cooper et al. [6] attached a mercury tilt switch to the sternum of a T11/12 paraplegic and used the signal to assist in controlling a two channel implanted stimulator (femoral and sciatic nerves). Tomovic et al.[20] used a pendulum inclinometer positioned on the shank of an active above knee prostheses in conjunction with footswitches to control knee damping. Petrofsky incorporated electrolytic tilt sensors into a prototype exercise bike for paralyzed subjects [14]. Symons et al. [19] investigated the feasibility of six FES trigger sources, including the vertical acceleration of the thigh for use with patients with incomplete spinal injury. Andrews et al. [1] used miniature inclinometers attached to a floor reaction type ankle foot orthosis as a source of biofeedback using an electro-cutaneous display to improve postural control during FES standing.

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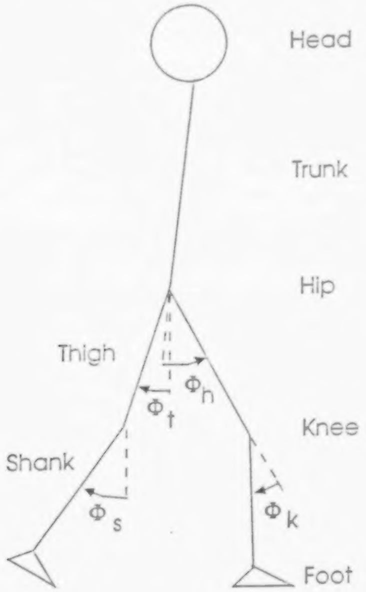
Willemsen et al. [21] described the use of accelerometers to distinguish stance and swing phase for peroneal nerve stimulation in hemiplegia based on cross correlation detection techniques. In addition, he described a real time technique for obtaining limb segment inclination signals from inclinometers without using integration for use in FES control and hemiplegic gait assessment. Bowker and Heath [3] suggested using a magnetotransducer to synchronize peroneal nerve stimulation to the gait cycle of hemiplegics by monitoring angular velocity.

Despite these several efforts no tilt sensors are currently being used to control functional electrical stimulation (FES) during movements such as walking. The most common method of control uses footswitches, as originally proposed by Liberson et al. [11], but this requires wires or telemetry [8] to connect the switch to the stimulator. Footswitches can not be used when walking barefoot and may function differently in different shoes or when walking over different terrain. Therefore, we decided to reexamine whether tilt sensors might have advantages for control of FES.

Since a tilt sensor measures the tilt of its axis with respect to a fixed reference, the joint angle of limbs or other body parts in principle can be measured with two sensors placed on either side of a joint. However, this provides no particular advantage over existing goniometers that are designed to measure joint angle. On the other hand, a tilt signal of a limb segment during walking may offer useful information for detecting the phases of the gait cycle. The convention defining the tilt angles of the lower limb is shown in Figure 3-1, in which the relations between the joint angles of hip and knee and the tilt angles of the thigh and shank are also defined.

The average angular motion of the knee and hip joints during a gait cycle for normal adults is shown in Figure 3-2, which is taken from [13]. Assuming that the trunk remains approximately vertical, the average tilt of the upper leg (thigh) and lower leg (shank) can be calculated (Figure 3-2B).The shank tilt shows a slow rising phase corresponding to forward leaning of the upper part of the segment that starts just before heel contact and a faster falling phase corresponding to backward leaning that starts after the toe comes off the ground. The heel comes off the ground at about 45% of the gait cycle when the shank is near the middle of the forward leaning phase. This offers the possibility of using the signal to trigger stimulation of subsequent gait events, such as stimulation of common peroneal (CP) nerve to lift the foot. Electrical stimulation was first introduced by Liberson et al [11] to prevent foot drop, thus, a population of stroke and incomplete spinal cord injury (SCI) patients who suffer from foot drop may benefit from use of tilt sensors. The tilt signal from the upper leg has similar characteristics, although shifted about 15% earlier in the step cycle. However, the rising phase of both tilt signals is very broad, spanning more than 50% of the gait cycle, so the timing of the threshold crossing may show considerable variability when used to detect certain gait events.

Figure 3-1. Convention for angles of the lower limb. The tilt of the thigh (Φ_t) and the shank (Φ_s) are shown with respect to the vertical. A forward lean of the upper part of the segment with respect to the lower part is shown as a positive value and a backward lean of the upper part of the segment as a negative value. In contrast the hip (Φ_h) and knee (Φ_k) joint angles are shown with flexion positive. When standing straight all four angles are near 0, but they diverge as motion begins.



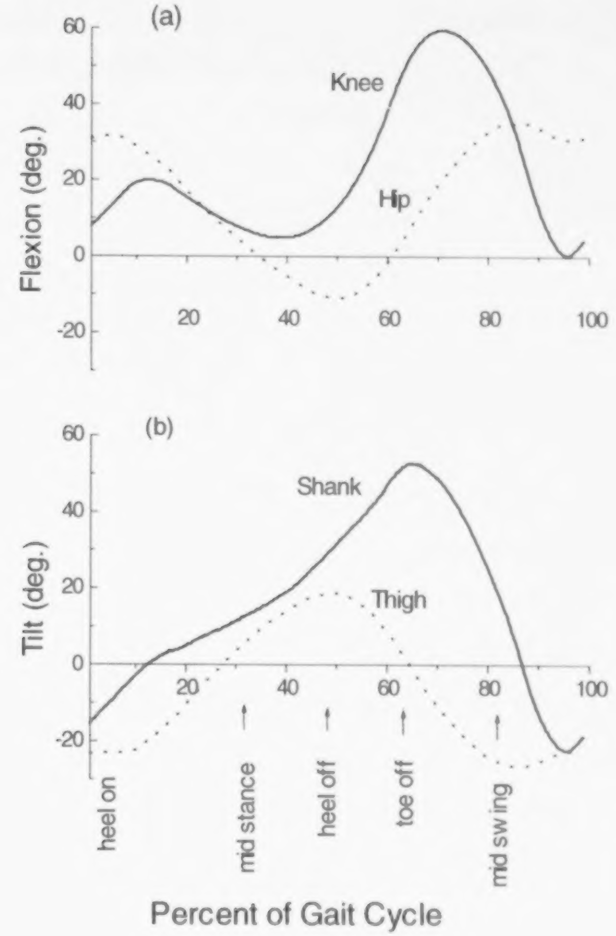


Figure 3-2. Leg motion during free walking, normalized to one gait cycle (Derived from Perry, 1992). (a) Angular motion of the hip and knee joints; (b) tilt motion of the upper leg (thigh) and lower leg (shank). See Figure 3-1 for a definition of these angles.

3.2 Methods And Materials

A tilt sensor normally uses inertia to detect the tilt from the gravity vector. It consists of an inertial element which senses gravity and a signal transforming element. Some sensors use a liquid inertial element, such as an electrolyte, magnetic fluid or mercury, while others use a pendulum or spring suspension system with solid elements. When the body of the sensor tilts, gravity causes a relative movement of the inertial element which is then converted into such as resistance, capacitance and current changes by various signal transforming techniques. The part sensing gravity usually determines the dynamic characteristics of a tilt sensor. The inherent problem of an inertial tilt sensor used in a dynamic environment is its response time and its response to accelerations. Non-inertial tilt sensors that use the earth s ambient magnetic field as a reference vector were also reported [8, 9]. But some specifications and requirements of these sensors, such as mechanical size, complexity of signal conditioning and high current consumption, prevent them from consideration in our current application. We tested three different, commercially available tilt sensors: 1) a miniature electrolytic tilt sensor (Model L-211U) from Spectron Glass and Electronics, Inc., (Hauppauge, NY); 2) two magnetoresistive tilt sensors (Model UA-1 and UV-1W) from Midori American Corp. (Fullerton, CA); and 3) a mercury tilt sensor (RS27) from COMUS International (Nutley, NJ). For our application the important sensor characteristics include physical size, mechanical reliability, signal stability of the sensor in a daily living environment and the simplicity of conditioning the sensor signal.

Table 3-1 lists the main specifications of the four models. The relations between the tilt angle and the normalized output of each sensor are shown in Figure 3-3. To use the sensor to detect gait events in an FES system, we need to consider the sensor s dynamic properties, as well as its temperature drift and mechanical reliability, etc.. The dynamic parameters of the tilt sensors were tested for each model. A lever system (Series 300B Lever System, Cambridge Technology, Inc. Cambridge, MA) was used to provide an angular input to the tilt sensor which was mounted at the center of rotation of the servo motor output arm to minimize the influence of acceleration to the sensor output. The angular movement of the lever was defined by a function generator which provided square wave and sinusoidal outputs in the frequency range 0.1 - 40 Hz. The step response settling time of the lever system was less than 15 ms. The input angle and the tilt output signals were recorded via an Axotape data acquisition system (Axon Instruments, Inc., Foster City, CA) using sampling rates up to 2000 Hz. To examine the response of the sensor to acceleration, we also did the same tests with the sensor mounted on the lever arm 3 cm from the center of rotation.

Figure 3-3. Sensor outputs vs. tilt angle. Sensors are directly excited with 5 Volts (DC for UA-1, UV-1 and RS27; 1 KHz AC for L_211U). Outputs are measured at the middle terminal and are normalized to 2.5 V at the middle position (zero degree of tilt).

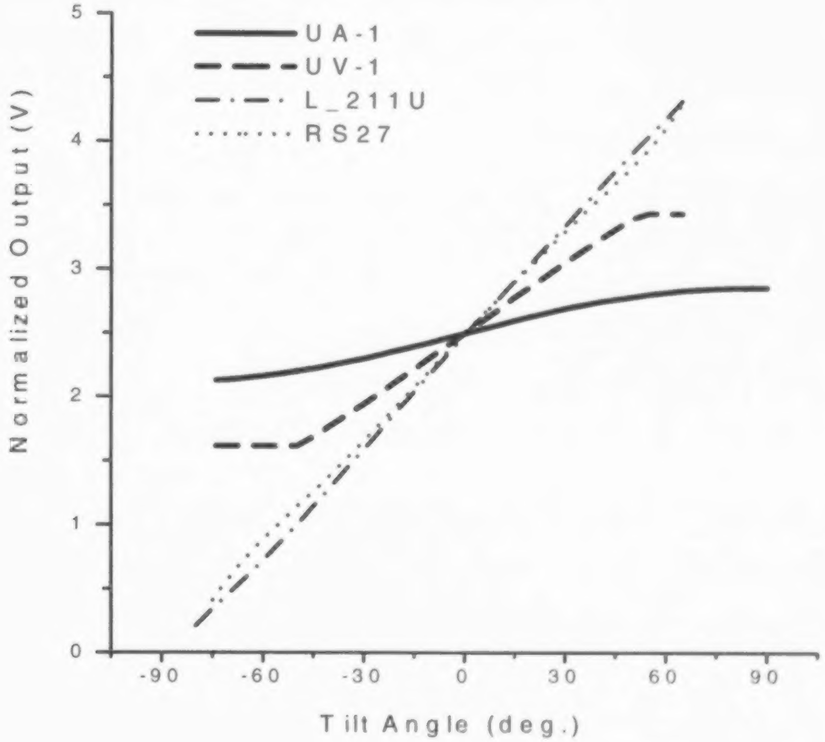


Table 3-1. **Specifications of tilt sensors**

Sensor	L-211U	UV-1W	UA-1	RS27
Type	Electrolytic	MR.	MR.	Mercury
Range of tilt ( )	+/-60 *	+/-50	+/-50 'em	+/-70
Sensitivity (mV/ /V)	7.2	3.7	1.27	5.4
Full scale Linearity (%)	5 *	1.5	3	3
Step Settling time (s)	0.5	0.2	0.5	1.5
Max. Excitation voltage (V) *	5 (AC)	<10	<8	<200
Temp. sensitivity (%/ C) *	<0.15	<0.1	'em	N/A
Max. Mechanical shock (g) *	N/A	50	3	100

*: data from manufacturer.**: linear range.***. see graphic results in Figure 3-6.

3.2.1 Electrolytic tilt sensor

Electrolytic tilt sensors are a traditional type of tilt sensors which have been used on aircraft and ships to provide signals for their guidance systems. This type of sensor has also been used in biomechanical research [15]. We tested the single axis miniature model Spectron L-211U which has a one piece glass enclosure approximately 1 cm in diameter. The three electrodes with internal platinum contacts and external terminals are sealed into the glass chamber. The internal chamber is partially filled with conductive electrolyte and a bubble is used to maintain direct contact with six internal walls to improve the signal stability when it tilts. The sensor functions like a liquid potentiometer, with the electrolytically conducting fluid creating a variable resistance between the electrodes. When the sensor is in a null or balanced position, the resistance between the center electrode and both outside electrodes is equal. Tilting the sensor from its balanced position changes the electrolyte proportion between the two sides of the middle electrode and therefore produces a resistance change proportional to the tilted angle. The electrolyte acts as both the sensing element and the signal transforming element.

The main advantages of the electrolytic tilt sensor are high resolution, wide range of angles of operation, and compact mechanical size. In response to a step tilt input, the sensor has a settling time of 0.5 sec. (Figure 3-4). In the frequency response, the gain has a cutoff frequency close to 9 Hz and an overall phase shift of 200 (Figure 3-5A). When tested at 3 cm from the center of rotation, the gain rises rapidly until the cutoff frequency is reached, after which the gain falls and severe dc shifting (hysteresis) in the output occurs (Figure 3-5B). Several disadvantages excluded them from further consideration for our FES application. The electrolyte conducts ion current and therefore the sensor has to be powered with an AC source because a DC excitation will cause electroplating of the electrolyte on the electrode terminals and will damage the sensor. The requirement for an AC source increases the complexity and cost of the signal conditioning circuit. The signal conditioner from the manufacture costs $125 or more each. In addition, both the sensitivity and offset biases of the sensor are temperature sensitive, which needs careful temperature compensation in order to use the sensor under the daily conditions in which an FES system must operate.

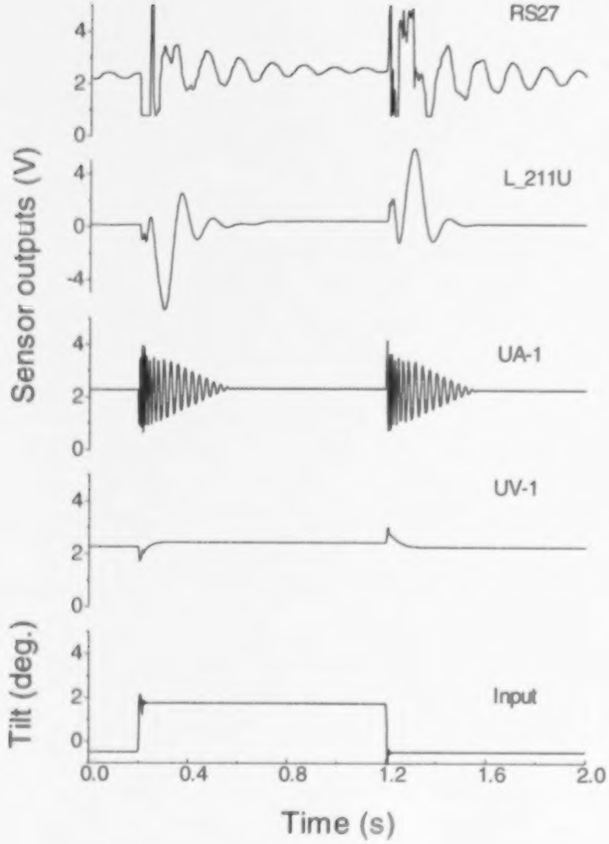


Figure 3-4 Step response of tilt sensors. Input is steps of 4° with a settling time of 10 ms. Sensors are powered with a 5 V source. Outputs are amplified with gain of two for UA-1, UV-1 and RS27, while L_211U uses signal conditioner MUPI-2 provided by the manufacturer.

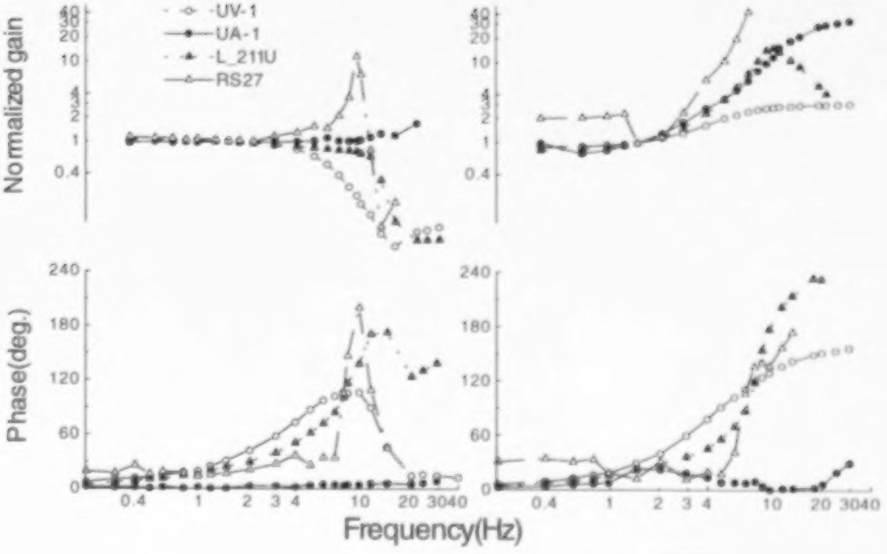
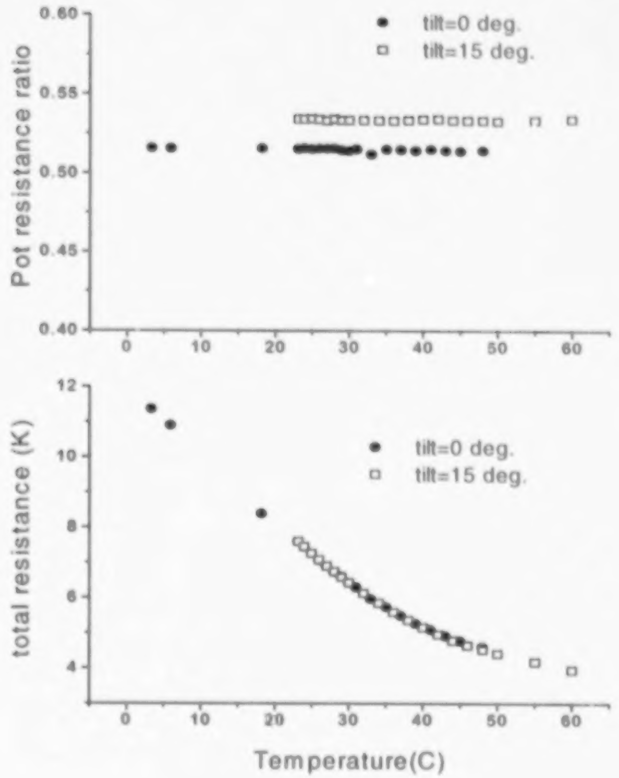


Figure 3-5. Frequency characteristics of tilt sensors. Data shown are sensor responses to +/- 2° sinusoidal tilt input generated by Cambridge B315 Lever System. Gain refers to the ratio of sensor outputs to the amplitude of tilt angle and the exciting voltage and is normalized to 1 at 1 Hz input frequency. Phase refers to the phase shift of the output signal with respect to the input. The two sets of data are collected with the sensor at the center of rotation (a) and moved 3 cm from it (b).

3.2.2 Magnetoresistive Tilt Sensors

Magnetoresistive (MR) elements have been used in angular sensors for applications such as detection of angular position of the steering wheel in automobiles. They are able to withstand high shock and vibration, presence of oil and dust and a wide range of temperatures [4]. MR sensors contain an MR element whose resistance changes with the magnetic field. An MR Element can be a ferromagnetic alloy whose electrical resistance depends on the direction of the magnetization vector, a phenomenon known as anisotropic magnetoresistive effect; or it can be a semiconductive material, such as InSb and GaAs, whose resistance changes with the applied magnetic flux density, a phenomenon known as the Hall effect. The MR tilt sensors we evaluated contain a thin film InSb MR element and two parallel pieces of permanent magnet that provide a constant magnetic field (200-300 Gauss) passing through the MR element in between the magnets. In model UV-1 the magnet pieces are attached to a pendulum which forms a mass of 1g. When the sensor tilts from the vertical direction, the mass moves toward the direction of gravity and rotates the pendulum which displaces the magnets over the MR element, The displacement of the magnets changes the magnetic flux density through the MR element. The resistance change of the MR elements then reflects the tilted angle. In model UA-1 the magnets are attached to a mass of 3 grams which is suspended by double springs. The tilt of the sensor body is converted to a linear displacement of the magnets over the surface of the MR element by the gravity and inertia force, which is reflected by a change in sensor resistance. The resistance change is proportional to the tilt angle of the sensor body over certain angular ranges. Both of the sensors can be treated as a three terminal potentiometer which greatly simplifies the signal conditioning requirement. The output of the MR element is temperature sensitive. The total resistance decreases dramatically when the temperature increases (by a factor of 3 between 0 and 60 C for UA-1), as shown in Figure 3-6A. However, the resistance ratio is essentially independent of temperature (Figure 3-6B)

Figure 3-6. Temperature influence on the output of UA-1. Lower graph (a) indicates the total resistance of the sensor (resistance between terminals 1 and 3), while upper graph (b) indicates the resistance ratio change when used as a potentiometer (R12 / R13). Each graph contains two sets of data tested with the sensor held at the zero and 15 deg. positions respectively.



Because of the difference in mechanical structures, the two sensors have different dynamic characteristics. In the UV-1W sensor the MR element and the pendulum - mass system are sealed in a cylinder case 22 mm in diameter and 16 cm in height which is filled with silicon damping oil (100CT/200CT) to reduce the acceleration component. It has a settling time of 0.2 s in response to a step tilt input. In its frequency response, the gain has a cutoff frequency of about 5 Hz, with an overall phase lag of 100 over the frequency range tested. When tested at 3 cm from the center of rotation, the overall increase of normalized gain is kept below three. In the UA-1 sensor, on the other hand, gravity sensing is achieved by a mass-spring system without any damping oil. The settling time of step response is 0.5 s (Figure 3-4). In its frequency response, the gain is steady until about 15 Hz when it starts to rise due to the increase of linear acceleration of the mass with the tilt frequency, while little phase shifting is introduced over the frequency tested (Figure 3-5A). When tested at 3 cm from the rotating center, however, the acceleration component dominates the output when the frequency increases and the gain rises more than 35 dB over the testing frequency range (Figure 3-5B). Finally, the output signal contains a resonance component near 30 Hz which results from the undamped double spring suspension in its mechanical structure. However, the basic frequency of human gait is about 1 Hz, which means that heavy, low-pass filtering can be used to reduce the acceleration effects and remove the frequency components near 30 Hz. Because of its miniature size, the UA-1 model is favored for our application in a pocket size FES device. However, the miniature model can only sustain about 2-3 g of mechanical shock. Special care must be taken mechanically when incorporating this sensor in a portable unit. The cost of a magnetoresistive tilt sensor is about $60, which is less than a half the cost of an electrolytic sensor.

3.2.3 Mercury Tilt Sensors

A mercury tilt sensor is so named because it uses mercury as the gravity sensing element. Unlike a mercury tilt switch that produces a binary signal (open or closed), the tilt sensor gives an output of variable resistance. We evaluated the tilt sensor Model VRS27 from COMUS International, which is mainly used to control the tilt angle of patient beds in hospitals. The sensor is basically a linear potentiometer in which a small drop of mercury of about 1g acts as a wiper. When the sensor tilts, the mercury drop, guided by gravity, slides along the inside surface of a round tube and remains in contact with the surface. One side of the tube s internal surface is plated with a film of resistive material with contacts at each end, while the other side is the metal case which is used as the wiper terminal. In this way, the resistance between the case terminal and the other two contacts varies with the angle of tilt.

The manufacturer only provided very limited data on the sensor s specification. Tested results show that, compared to the magnetoresistive sensor, the mercury sensor has lower temperature sensitivity, excellent response axis selectivity and high mechanical shock resistance. Because of the use of liquid mercury, the sensor has a lower resolution and poorer repeatability than MR sensors in spite of its higher sensitivity. Testing also indicates the longest settling time among the four sensors tested (>1.5 sec; Figure 3-4). The frequency response shows a pole at about 7 Hz with a peak in gain and a phase jump (Figure 3-5A). When placed at the eccentric position, the gain rises sharply with frequency and is only limited by the excitation voltage and mechanical characteristic of the sensor (Figure 3-5B). Severe signal distortion and DC shifts are also observed in the output signal when the frequency increases. The 7 Hz resonance is much closer to the frequencies of interest during walking, but can still be filtered out to some extent. However, the long settling time will limit the sensor only to respond well to subjects with very slow walking speed. An additional problem to be considered with the mercury sensor is that it causes an instant short circuit at the sensor terminals when the sensor is mechanically shocked, such as at heel strike in our application, or placed on the horizontal plane. Processing the data from a mercury sensor is similar to the MR sensor, since both function as potentiometers. The cost of a mercury sensor is about half of an MR sensor.

3.2.4 Tilt sensor to record walking

As shown in Figure 3-2, the shank tilt signal can be correlated with the foot contact events. The heel contact corresponds to the beginning of the rising phase of the tilt signal while heel off is about half way up the rising slope, which gives the possibility to use the tilt sensor to detect the intention to take a step, as is commonly done with heel switches. The tilt sensor can be positioned at some point on the leg, such as medial to the tibia where the skin motion is insignificant, with Velcro tape or it can be built directly into a stimulator. In order to measure the entire range of motion, the tilt sensor is positioned so that its lowest output point will be about the heel contact position when the top of the shank is tilted farthest back during the step cycle. Then, the signal will rise as the body moves forward over the leg. Force sensing resistors (FSR, Interlink, Inc., CA; 0.875") are placed in the insole of a shoe at the heel and toe to provide reference points for the step cycle.

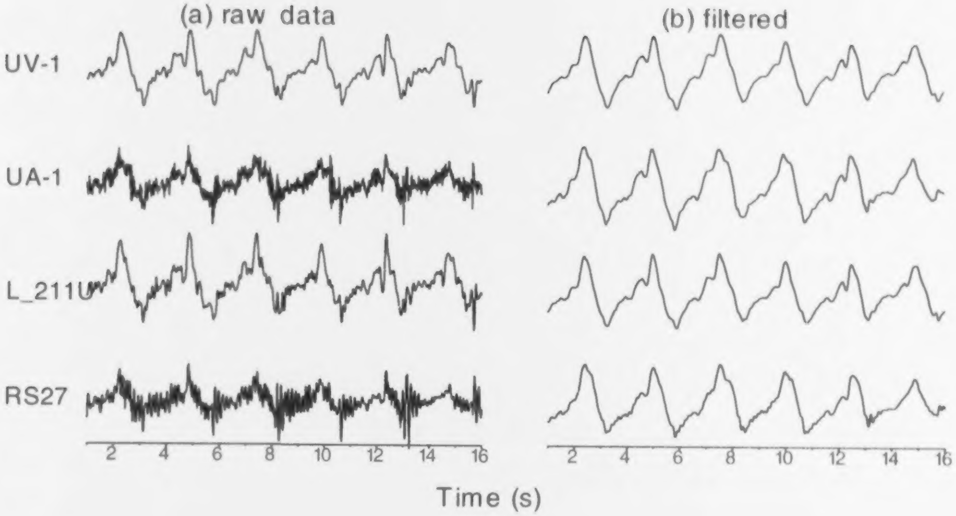


Figure 3-7. Sensor signals in a walking trial. Data are recorded with the 4 sensors fixed on the lower leg at a position about 5 cm from the knee joint simultaneously. The control subject is doing level walking at a slow speed close to 0.5 m/s. (a) Unprocessed sensor signals; (b) signals filtered with a second order lowpass RC filter of 1.5 Hz for RS27 and 2 Hz for others.

The MR and mercury tilt sensors (3 terminals) can be simply used as a DC voltage divider with necessary temperature compensation and gain circuitry to condition the signal. The electrolytic sensor, on the other hand, has additional circuitry requirement such as AC excitation and signal demodulation etc.. Unprocessed data of the 4 tilt sensors recorded with standard interfacing circuitry from a walking trial with a control subject is shown in Figure 3-7, which includes a substantial high frequency component in the signals from the miniature MR sensor UA-1 and the mercury sensor. Using a second order low pass RC filter can effectively retrieve the gait signal without introducing substantial delays or significant distortion. The cutoff frequency is typically 2 Hz for the MR and electrolytic sensors and 1.5 Hz for the mercury sensor.

We chose the UA-1 miniature MR sensor for our application in a small, self-contained FES device for its compact size, low cost, simplicity of use and reasonable signal quality. To minimize the effect of temperature change on sensor output the sensors were powered directly from a precision 1.25V DC voltage source. Signal conditioning involved an operational amplifier to provide gain and offset of the sensor output. The entire circuits were powered from an AA NiCad battery. For signal analysis, all necessary outputs were feed to a IBM - compatible personal computer from the FES device using Axotape and a sampling rate of 50 Hz.

3.3 Results

3.3.1 Data from control subjects

The correlation between the signal of a tilt sensor on the shank of a control subject walking slowly and the foot contact events can be shown by simultaneously recording the signals of the heel and toe FSR s on the same side of the body. Normalizing the data to one gait cycle, as shown in **Figure 3-8**, gives a closer look at the tilt signal. Instead of a smooth signal as shown in Figure 3-2b, there are two oscillations on the rising slope. The first one corresponds to the shank acceleration after mid stance when the knee extends the second time. The second oscillation is caused by the shank acceleration after the heel off. A forward acceleration will cause a decrease of the tilt sensor output. Thus, the deceleration following an acceleration will cause a steeper rise of the output. At the toe off, the shank first accelerates in the backward direction, which steepens the signal falling phase. In a subject with foot drop, visible oscillations may also occur when the foot strikes the ground and when the stimuli turns on and off (Figure 3-9 and 10). The actual output signal of the tilt sensor has been filtered at 2 Hz with a second order RC low-pass filter, which means the tilt signal is actually delayed with a time constant of 0.15 s. It can be seen on the graph that the heel off is now located at the steep segment which is about 10% of gait cycle in length between the two oscillations on the rising slope of the tilt signal. The shank accelerations during forward leaning therefore allow a threshold to be adjusted on the tilt signal to trigger a stimulation without introducing too much timing variance. In fast walking, however, this correlation may disappear and the delay of the tilt signal caused by filtering may be too great, but the patient population are generally unable to walk at fast speed.

As the leg swings through after toe off, the tilt sensor continues to give dynamic information. If we are directly stimulating certain nerves or muscles to assist the step, it will be important to have the stimulus duration set properly. The tilt sensor provides this possibility since, as shown in **Figure 3-8**, the falling slope may be used to turn off the stimulus. To do this, an adjustable "hysteresis" can be combined into the threshold detection protocol so that the stimulus is turned on at one leg position and off at another before the foot contact. Setting the hysteresis can also prevent the stimulation from being turned on and off instantly by noise in the signal or clonus in the patient s gait.

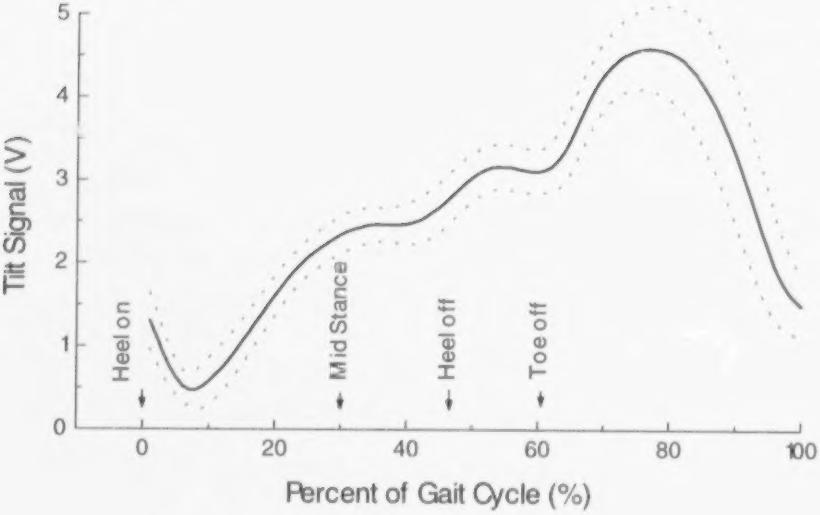


Figure 3-8. Lower leg tilt signal of a normal subject in one gait cycle. Tilt sensor UA-1 is used with the same conditions as in Figure 3-7. Signal are lowpass filtered at 2 Hz. Dotted traces indicate the standard deviation about the mean (solid trace) throughout the cycle.

3.3.2 Data from subjects with foot drop problems

Recordings have been made from a group of six subjects with spinal cord injury or stroke who had problems of walking, including foot drop. In order to walk these subjects use either an ankle foot orthosis (AFO) which is a plastic brace that maintains the foot in a dorsiflexed position or FES to provide foot clearance.

Figure 3-9 shows data recorded from a female subject walking with FES. A Midori UA-1 tilt sensor was placed on the shank close to the knee to record the tilt signal, as well as FSR s at the heel and toe for force signals. She sustained an incomplete SCI at C1/C2 with motor deficits that prevents her from advancing her left leg during swing without the assistance of FES. With the control of a hand switch, stimulation was conducted to the CP nerve of her left foot with a fixed delay of 200 ms. Nevertheless, her speed of walking is at the low end, about 0.1 m/s; and step cycle about 4 s.. She has to walk with a walker, which results in a different pattern of sensor signals. By setting a threshold on the tilt signal and a maximum duration, we get a simulated switching signal controlled by the tilt sensor. The correlation between the two switching signals is obvious from the graph. The timing of the control signal from the tilt sensor can be adjusted by properly shifting the threshold. For example, it is 100 ms ahead of the hand switch signal on average with a standard deviation of 190 ms when setting the threshold at 0.8 V as shown in Figure 3-9. The signal consistency is shown in Figure 3-9B, in which the tilt signals of each gait cycle are superimposed together with the onset of a hand switch as the reference point.

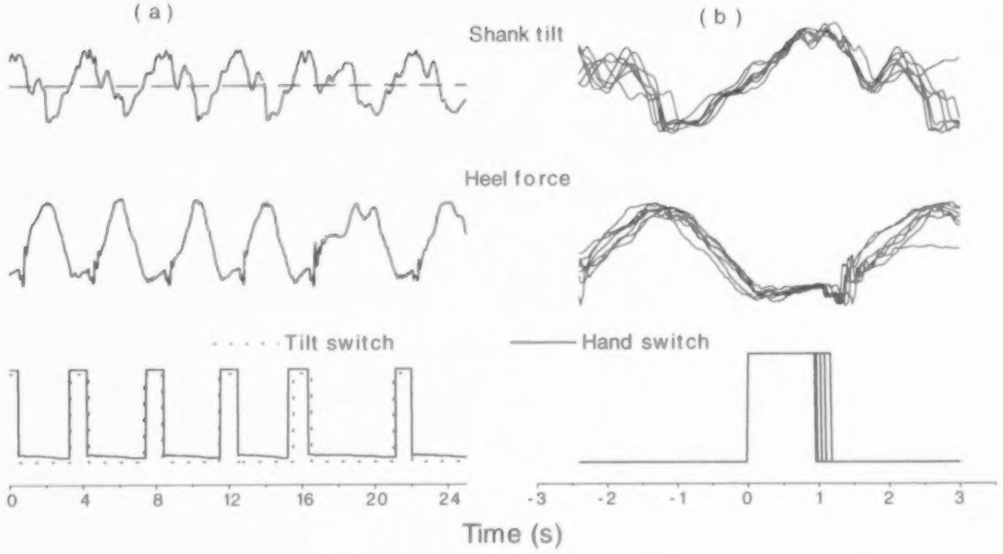


Figure 3-9. Data recorded from a female subject with incomplete SCI. The subject walks with the help of a walker and stimulation conducted to the CP nerve of her left leg by a hand switch (lower trace). (a). Tilt signal is recorded with a UA-1 sensor on the medial side of her lower left leg. Dotted traces indicate a simulated control with the tilt signal using a threshold. (b). Tilt signals of each gait cycle are superimposed together with the onset of the hand switch as the reference point.

3.3.3 Controlling the stimulation with tilt sensor

A control protocol using the finite state method to control the stimulation with a tilt sensor detecting the shank or thigh movement is described below. The stimulus is turned on when the tilt signal rises above the ON threshold which corresponds to a predefined forward leg position. The stimulus will be turned off either if the tilt falls below a second level or if a preset maximum duration is exceeded. A lockout state is entered following the stimulus to prevent the stimulation from being turned on by signal peaks that occur in some subjects. A second stimulus can only be turned on after the leg has fallen below the second level so that a repetitive stimulation will not occur if the leg rests in a forward position.

Data shown in Figure 3-10 was collected from another female subject walking with FES controlled by a tilt sensor on the shank with the above protocol. The subject suffered a stroke two years ago that left her with residual right foot drop and she had to use an AFO for activities outside the house. The signal from the tilt sensor shows a similar pattern to the control subjects shown in **Figure 3-8**, with an extra peak on the falling slope which is caused by the stimulus and another small peak caused by foot strike at heel contact. The ON threshold was adjusted to 1.4 V with a hysteresis of 0.55 V. The tilt signal turned the stimulus on 0.17 ± 0.15 s before the heel came off the ground, and turned it off 0.05 ± 0.04 s after the heel contact. The stimulus duration was 1.2 ± 0.11 seconds, and step cycle is 1.9 ± 0.25 seconds. Note that the timing to turn the stimulus off can be adjusted to the most comfortable point by increasing or decreasing the OFF threshold. In this way, the stimulus duration can be adapted to the walking speed. With the FES controlled by a tilt sensor, she can walk as fast as with an AFO, but without the difficulties and bulkiness.

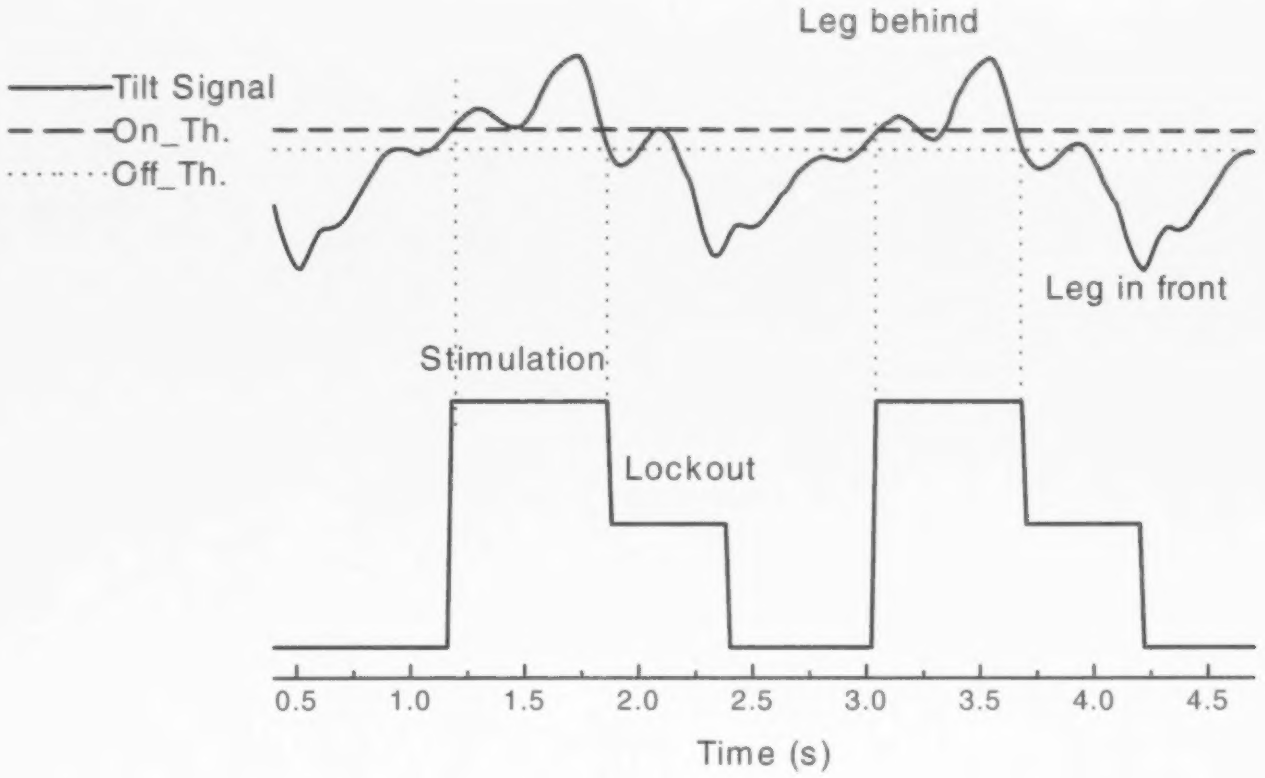


Figure 3-10. Controlling the stimulation with tilt sensor. Signals are collected from a stroke subject walking with the help of a footdrop stimulator controlled with a UA-1 tilt sensor on her right lower leg. The control method is described in the text.

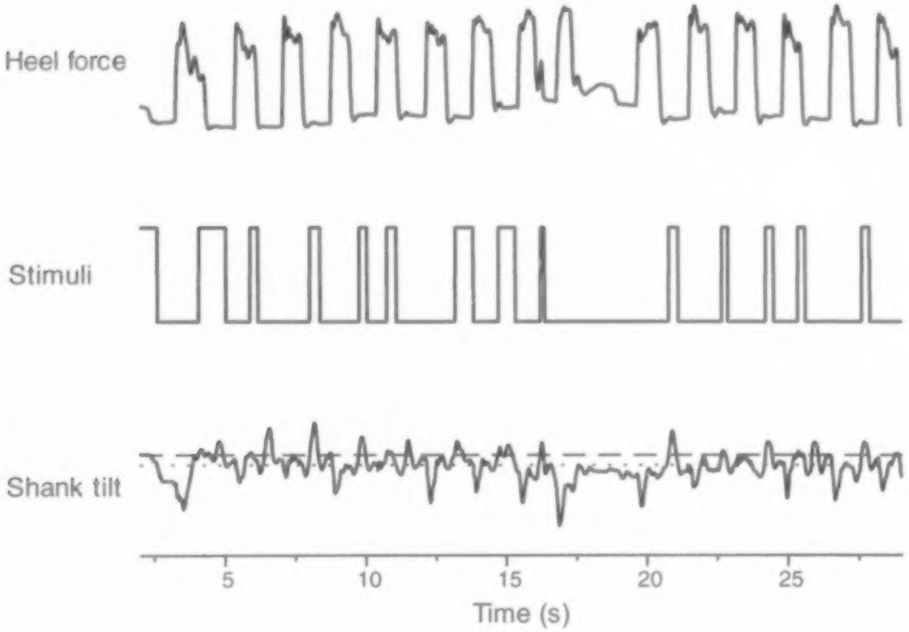
3.4 Discussion

There is a significant population of individuals suffering from a stroke or an incomplete SCI who may benefit from using FES to improve their gait quality. However, most of them still rely on an AFO to walk functionally. FES needs to be superior to an AFO in ease of use and reliability in order to be accepted by this population. The control of the stimulation, which contributes an important aspect of the reliability, is mostly confined to a suitable sensor that provides the control signal. Using a foot switch or sensor is adequate to trigger the stimulation automatically in incomplete SCI subjects without severe complications due to spasticity or clonus [18]. The foot sensors are easy to don and reasonably durable [10]. However, the sensors have to be fitted in an insole in the shoe in order to detect the contact, which limits the subject to wearing shoes as with an AFO. In addition, the requirement for external wiring from the sensor to the stimulator presents a high possibility of breakage which will cause the stimulator to fail . It also makes it difficult to get a good cosmesis using FES, which is very important for subjects in this population in addition to improvement in function.

Tilt sensors provide the control signals by detecting the absolute angular displacement of a leg segment. Unlike the foot switch method, however, the contactless approach eliminates the requirement of wearing shoes and still remains easy to don and doff. Using the above control protocol with tilt sensors, our initial trials with stroke and SCI subjects showed that tilt sensors can replace foot switches to control FES in preventing foot drop and improving the quality of gait in individuals with stroke or incomplete SCI.

Tilt sensors also provide a possibility to eliminate external wiring from the sensor to the controller as normally required with foot sensors. We have designed a prototype pocket size footdrop FES device using the above control protocol and a tilt sensor built in the device, which means that no sensor cable or switch is needed to get the control signal. The unit may be attached to the lower or upper leg and calibration is simple. The use of a tilt sensor promises a good cosmesis, ease of use and increased durability compared with contact sensors. Subjects with a foot drop problem resulting from either a stroke or incomplete SCI have participated in the initial testing. They have some initial gait ability with or without an AFO. The results with the initial testing is very encouraging (See Chapter 4 for details), so that a formal clinical testing program in stroke subjects is initiated in Edmonton (See [22]).

Figure 3-11. Data recorded from a stroke subject with knee movement difficult. The tilt signal of the lower leg has a reduced amplitude and does not show a regular pattern. The triggered stimuli has significant errors and is out of phase compared to the heel force signal which is recorded with an FSR placed at the heel.



The use of double thresholds in the control protocol with tilt sensors also increases the noise rejection level, which makes it suitable for subjects with spasticity or clonus. However, this control method is still confined to subjects who suffer mainly from foot drop but who have some initial gait abilities with changing orientation of leg segments. Figure 3-11 shows a case where this method does not apply well. The subject suffered a stroke that left him with foot drop and difficult of extending his left knee. The limited swinging movement of his lower leg was expressed as a small, erratic tilt output from the shank which produced errors in detecting step intention. More robust control with tilt sensors may be achieved by using a different technique, such as machine learning. [2, 10, 16].

Tilt sensors provide a useful signal method to describe the gait events in real time. The application of tilt sensors in functional electrical stimulation is not confined to the population we described here. They can also be combined with other sensors such as an FSR or accelerometer, to achieve robust control of FES to assist or improve the gait of individuals with different walking difficulties.

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4. FUNCTIONAL ELECTRICAL STIMULATION FOR WALKING OF SUBJECTS AFTER INCOMPLETE SPINAL INJURY---A GAIT ASSESSMENT[1]

___ Gait analysis of Edmonton subjects in multicenter clinical testing ___

4.1 Introduction

Liberson [1] introduced the use of electrical stimulation to prevent foot drop in stroke patients over 30 years ago, which led to the application of this technique, now known as functional electrical stimulation (FES), in restoring or improving of locomotion of spinal cord injured (SCI) and other groups who have lost supraspinal control of α-motorneurons. FES is also finding increasing clinical use in a variety of areas including restoration of respiration, bladder, bowel and sexual function, exercise and hand grasp. At least four channels of stimulation are required for restoring walking after complete SCI, with two channels applied to the quadriceps for stance phase and the other two channels to the common peroneal nerve to elicit the swing of the ipsilateral limb. More channels of stimulation may be needed for greater speed, better gait control, or other functions such as climbing stairs [2],[3]. Systems with more than 4-6 channels are complex enough that they have only been applied on a research basis.

FES has greater potential for functional use in incomplete SCI subjects and hemiplegic subjects due to the preservation of some motor and proprioceptive function such as initiating a gait and maintaining balance. Simple 1-4 channel

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[1] * This report was prepared for the “multicenter clinical trials of stimulation systems for walking” in Edmonton, July, 1995. Revised in July, 1996.

FES systems with surface or percutaneous electrodes have been useful in improving the gait qualities in this population [4]-[9]. In 1992 Stein et al [6] assessed the use of relatively simple FES systems on a group of incomplete SCI subjects. Two major results emerged from this study. First, the subjects were able to increase their walking speed significantly, but the average increase was less than 0.1 m/s. Second, the walking of these subjects was quite costly energetically, irrespective of whether they used FES or not. Despite these limitations the benefits were sufficient that a multi-center trial was initiated by adding other centers across Canada [12]-[14].

Overall, the goals of this study were to: 1) evaluate simple FES systems for walking, 2) study their acceptance by disabled subjects, 3) assess any limitations to wide-spread acceptance of FES systems by these subjects, and 4) develop improved systems that might overcome the limitations.

A total of 29 subjects were studied in the multi-center trials, of whom 27 with incomplete spinal cord injury, one with stroke and one with head injury. This report is based on the gait evaluation work done in the Edmonton center.

4.2 Methods

4.2.1 The subjects

Seven subjects were studied, of whom 5 had suffered an incomplete spinal cord injury, one had suffered a head injury and another a stroke. The two subjects with head injury and with stroke presented clinically, in terms of their motor deficits, similarly to the incomplete SCI subjects. One of the SCI subjects suffered another injury during the study period; therefore he was excluded from the study. Injury details of the six subjects are given in

Table 4-1, which also shows their initial walking speed without FES. All SCI subjects, except the one with stroke (subject 5), had at least two years of post injury when they were enrolled into the FES program, so that the subjects had reached a stable situation in regard to their physical deficits and psychological adjustment to their injuries. Subject 5 suffered a stroke in May 1993. She had recovered to a state with a near normal upper extremity and a residual weakness on her right ankle and knee flexion when she entered the FES program in March 1994. All subjects could stand unassisted and all but one of the subjects (subject 1) could walk to some extent with their principal walking aids, but without FES. Three used crutches, two used canes and two used walkers as their principle walking aids when they entered the program. One subject had to use a knee-ankle-foot-orthosis (KAFO) when walking. Initial walking speed without FES was taken as the average data of all the measurements made within the first month after beginning the program in order to minimize the factors that might affect the walking of a subject on individual days.

Table 4-1. Subject details

Subject	***LW***	***CC***	***CH***	***LS***	***CE***	***SA***
Date of Birth	8/47	11/67	1/57	12/37	7/41	8/57
Date of Injury	10/86	3/86	6/88	10/89	5/93	3/82
Cause of Injury	AVM	MVA	Diving	TM	CVA	GSW
Level of Injury	C2	C3/4	C4/5	T9	R. Hemi.	L. Hemi.
FES Entry Date	1/90	4/92	1/90	5/92	3/94	7/93
Stim Chan/Type	4/Percu.	1/Surface	1/Implant	1/Surface	1/Surface	4/Percu.
Stim Side/Site	L/CP,GL,Qu	L/Qu	L/CP	R/CP	R/CP	L/CP,Ham.
Walking Aids	Walker	Crutch	Crutch/Cane	Walker	Cane	Cane
Bracing	N/A	Shoe lift	N/A	N/A	AFO	AFO/Aircast
Initial Speed(m/s)	0	0.42	0.36	0.25	0.52	0.69

4.2.2 Stimulation

The FES systems ranged from 1 to 4 channels using either surface or percutaneous electrodes to deliver the stimulation. Stimulation was provided by either the "Unistim", a 1 channel stimulator, or the "Quadstim", a 4 channel stimulator. These stimulators were produced in Edmonton (Biomotion, Ltd.). The Unistim contains timing circuits to set the duration of the stimulus and to prevent unwanted, rapid retriggering due to clonus. The Quadstim is a rugged, high power (140 mA) stimulator that is more reliable than the earlier versions. Control of these devices can be by either hand or foot switches. The Unistim can accommodate other sensors such as force-sensing-resistors (Interlink Electronics, Santa Barbara CA), while the Quadstim has an interface that allows computer control.

If the subject showed "foot drop" (i.e., the foot dropped and dragged on the ground during the swing phase), then stimulation was applied to the common peroneal nerve. If the resultant ankle dorsiflexion was not sufficient, then the stimulus intensity was increased in some subjects to elicit a flexor reflex that also activated hip and knee flexors. Subjects used Multiweek self-adhesive, surface electrodes (Chattanooga, TN) or the equivalent for stimulation. In two of the subjects (subject 1 and 6), percutaneous electrodes were implanted to the CP nerve and muscle groups such as tibialis anterior, quadriceps and lateral and medial hamstrings in a later stage. The implants were made of Cooner 632 stainless steel fine wires (Cooner, USA) and the manufacturing was described in [10]. They were placed transcutaneously through hypodermic needles in the day surgery of the University of Alberta Hospital.

4.2.3 Gait Analysis

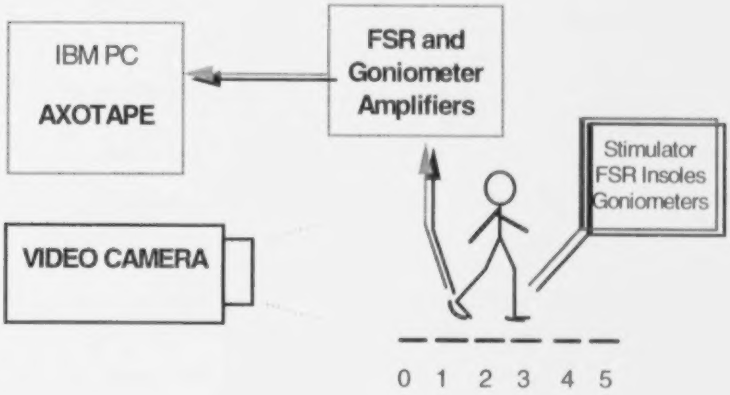
4.2.3.1 Instrumentation

Variables of interest for a detailed gait analysis could include ground reaction forces, the pressure distribution beneath the foot, temporal parameters of walking, limb trajectories and the EMG activity, etc.. To assess the gait performance of subjects using the single to 4 channel stimulators, we mainly use three gait signatures: average speed, stride length and stride time (gait cycle). They can be extracted from the temporal and spatial foot contact information. In most of the subjects from Edmonton, joint angle at hip, knee and ankle are also monitored to determine the gait abnormality, optimal stimulation intensity and site, and gait progress factor. The setup for the gait analysis lab is shown in Figure 4-1, which includes a video camera, goniometers at hip, knee and ankle joints, insole FSR force sensors at both feet, and the instruments that interface to a computer for data acquisition.

To determine the temporal stride phases, we use an insole made of thermal plastic TEPP2 [17] instrumented with four FSR sensors at the heel, toe, medial and lateral metatarsal positions, as shown in Figure 4-2a. A similar configuration using FSRs to provide feedback signals was first reported by Andrews, et al [12]. In the normal situation, the FSR's at the heel and the toe will give heel-on and toe-off signals that determine the stance time, swing time and the stride time, as shown in Figure 4-2b. In a situation such as flat foot or with an AFO, the other sensors may give cleaner signals of forefoot contact.

To measure the joint angles, we use the flexible strain gauge goniometers manufactured by Penny and Giles Biometrics Ltd.. With three dual axial goniometers across the hip, knee, and ankle joints, we are able to monitor the hip flexion, hip abduction, knee flexion, ankle dorsiflexion and ankle eversion of the disabled leg. The goniometer design allows us to directly attach them to the subject's skin via adhesive medical tape. Calibration is needed for each attachment. Because of the variability of each step along the course of walking, the angle signals for each walking condition are usually normalized and averaged to one gait cycle, as shown in Figure 4-4. In some cases, such as with recording done in other centers, direct measurement from the videos are also used to measure the range of the joint angles.

To measure the stride length and speed, we use a video camera and marked walkway. The measurement is done off line on video tape, by measuring the spatial and temporal points of foot contact. This method is simple and low cost, although not very accurate. For our application, it fulfills the requirement for measuring the static values such as stride length and average speed. However, for dynamic information, the sensor data should be synchronized with the video image.


IBM PC
AXOTAPE
FSR and Goniometer Amplifiers
Stimulator
FSR Insoles
Goniometers
VIDEO CAMERA
0
1
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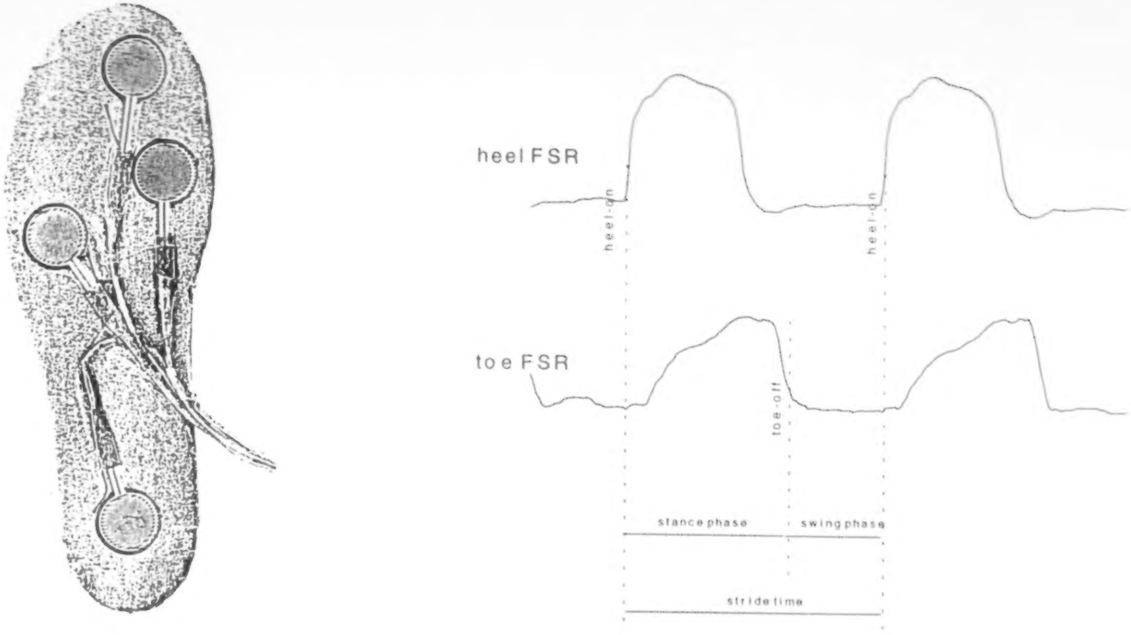
4
5

Figure 4-1. Gait analysis setup: 1) FSRs at the insole measures the heel-on and toe-off timing; 2) Goniometers measure joint angle trajectories at hip, knee and ankle of the disabled leg; 3) Video camera and marked walkway record the foot spatial information; 4) FSR and goniometer data are recorded by the computer through sensor interfacing circuitry.


heel FSR
heel-on
heel-on
toe FSR
toe-off
stance phase
swing phase
stride time

(a)

(b)

Figure 4-2. a). A thermal plastic insole is instrumented with 4 FSRs in order to locate the most significant signals for heel-on and toe-off. b). **Stance phase** is measured from heel-on to toe-off, **swing phase** is from toe-off to heel-on, and **stride time** is the sum of both.

4.2.3.2 Measurement

Subjects were asked to walk safely, as rapidly as possible with and without FES along the marked pathway under a video camera. Where subjects used more than one type of walking aid or brace, the effects of each assistive device were also analyzed. Typically, 4 stretches of about 5 m of walking were analyzed for each condition, and the conditions were interleaved to minimize the effects of fatigue. The availability of subjects for gait analysis varied with their distance from Edmonton, their family and employment situation, etc. The program period is basically 6 months, but a subject may stay in the program if he or she wants to. Some subjects who were of particular interest have been recorded many times over periods extending for more than 3 years. For comparison and statistical analysis across the subjects, the various sessions were divided into three groups for analysis: initial (<1 month), intermediate (2-4 months) and final (≥5 months). Where multiple sessions were available within these time intervals, results were averaged. When changes were significant because of change of condition, such as from surface stimulation to percutaneous, only the data with the same condition were grouped together. Grouping may underestimate the overall changes, since significant changes within the first month or after the fifth month were also noticed. However, from a statistical point of view, using an average is considered to be more accurate than taking values from a single session.

Over all 5 m segments, 2) stride length (m), averaged over the same steps for the more affected leg, 3) cycle time (from heel contact with the more affected leg to the next heel contact) averaged over the same steps, 4) stance time from "foot on" to "foot off", and 5) swing time, when the foot is in the air, which is simply the difference between stance and cycle times. Recording from a typical walking session is shown in Figure 4-3.

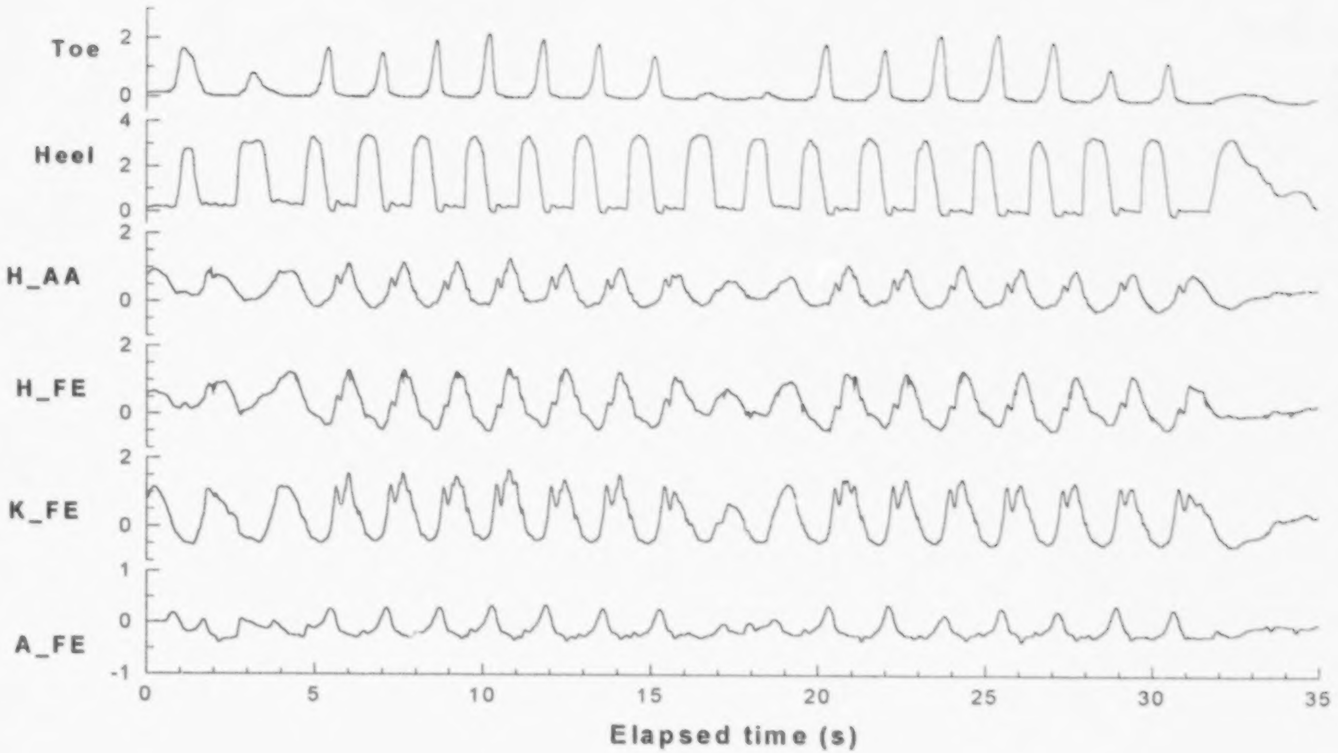


Figure 4-3. A typical stretch of recording. The middle part is when the subject is turning around. Goniometer signals are: A_FE=ankle dorsiflexion-plantarflexion; K_FE=knee flexion-extension; hip_FE=hip flexion-extension; H_AA=hip abduction-adduction. Foot pressure signals are: Heel=heel FSR output, and Toe=toe FSR output.

4.3 Results

4.3.1 Subject SA

SA was initially seen in March 1993. He presented with left hemiparesis following a gunshot wound to the right parietal lobe in March 1982. His left upper extremity was completely non-functional. His left lower extremity is partially paralyzed with weakness in all of the muscle groups which significantly affected his ambulation. He also has clonus in his left ankle. He had only a flicker of muscle activity in Tibialis Anterior so that he had to wear an AFO. During left swing phase he circumducts with a straight leg and during stance phase, due to poor quadriceps and hamstring strength, he hyperextends his knee to lock it. He used a straight cane to assist his walking and was able to walk up to three kilometers at one time, but pain (general pain inside his left knee) and fatigue often limited his locomotion range. He was seen at the Edmonton General Hospital Physiotherapy Department in May, 1993 for a four week course of gait training. In June 1993 he was reevaluated in our lab and was accepted into the FES program. His initial walking speed without stimulation was 0.69 m/s.

Surface electrodes over the CP nerve elicited a satisfactory dorsiflexion. He was given a single channel Unistim stimulator which was triggered by an FSR heel switch. The rising edge of the FSR signal showing heel lift (onset of terminal double stance) is used to trigger the stimulation after a preset delay period to assist dosiflexion of the ankle during the swing phase. Weekly gait analysis showed quick improvement of his walking speed with this single channel FES device. A second channel was added to the hamstrings 12 weeks later which appeared to facilitate the knee flexion. Figure 4-4 shows that adding the second channel did not significantly increase the knee flexion range but the knee flexion duration during the swing phase, which gave a better ground clearance throughout the swing phase. Gait analysis also showed that his walking speed was further increased to close to 1 m/s by both the increased stride length and the decreased stride cycle with addition of the second channel.

To avoid the hassle of daily locating the stimulating sites with the surface electrodes and to improve the cosmesis, SA expressed an interest in having his electrodes implanted to the stimulating sites. In Nov. 1993, percutaneous electrodes were implanted in the TA and hamstrings muscles and by the CP nerve. As shown in Figure 4-5, with percutaneous electrodes his gait speed (data from Nov., 1993) was kept close to 1 m/s but was not further improved over the 2 channel surface electrode configuration. He used the system daily for about half a year until problems with electrode breakage occurred. In October 1994 SA withdrew from the program.

Figure 4-5 displays SA's gait performance over the one year period, in which it shows a steady increase in his walking speed both with or without FES, which is associated with both an increase in stride length and a decrease in stride cycle time. The figure also shows that the improvement of his gait parameters seemed to logarithmically follow the time course, characterized by a fast initial progress followed by a more smooth slope. This was true for most subjects. As shown in Table 4-2, the overall increase of speed with FES and a cane is 65%, which resulted from a 25% increase of stride length and 24% decrease of stride cycle time. The statistical significance of the gait improvement of the subject is examined with independent (unpaired) two tailed t_test with all the walking stretches within the initial period and all those within the final period under the same walking condition. Results showed that changes of speed ($P<0.01$), Stride length ($P<0.005$) and stride cycle time ($P<0.01$) are significant for walking with FES.

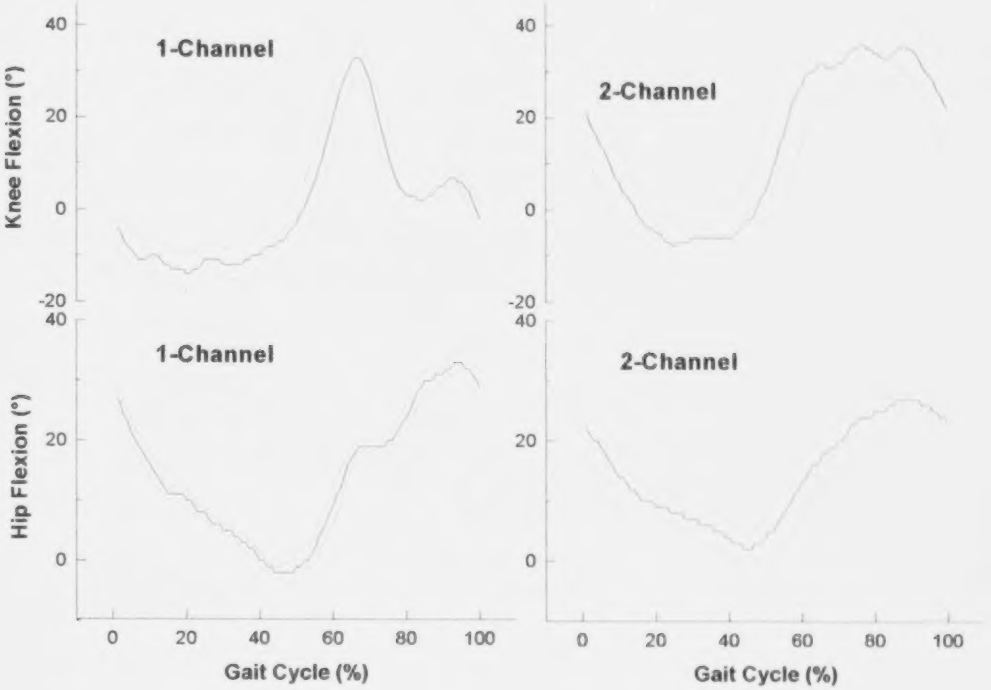


Figure 4-4. For SA, adding a second channel of stimulation to hamstring did not significantly increase the knee flexion range but the knee flexion duration during the swing phase, which gave a better ground clearance throughout the swing phase. Hip flexion is not increased.

Table 4-2. Gait performance of SA

CONDITION	FES		NO FES		BRACING	
Stage	*INITIAL*	*FINAL*	*INITIAL*	*FINAL*	*INITIAL*	*FINAL*
Speed	0.57±0.03	0.94±0.05	0.68±0.05	0.74	0.75±0.06	0.96±0.02
Stride	1.01±0.03	1.26±0.02	1.09±0.04	1.12	1.17±0.01	1.23±0.02
Cycle	1.77±0.05	1.35±0.07	1.59±0.06	1.50	1.57±0.14	1.29±0.01

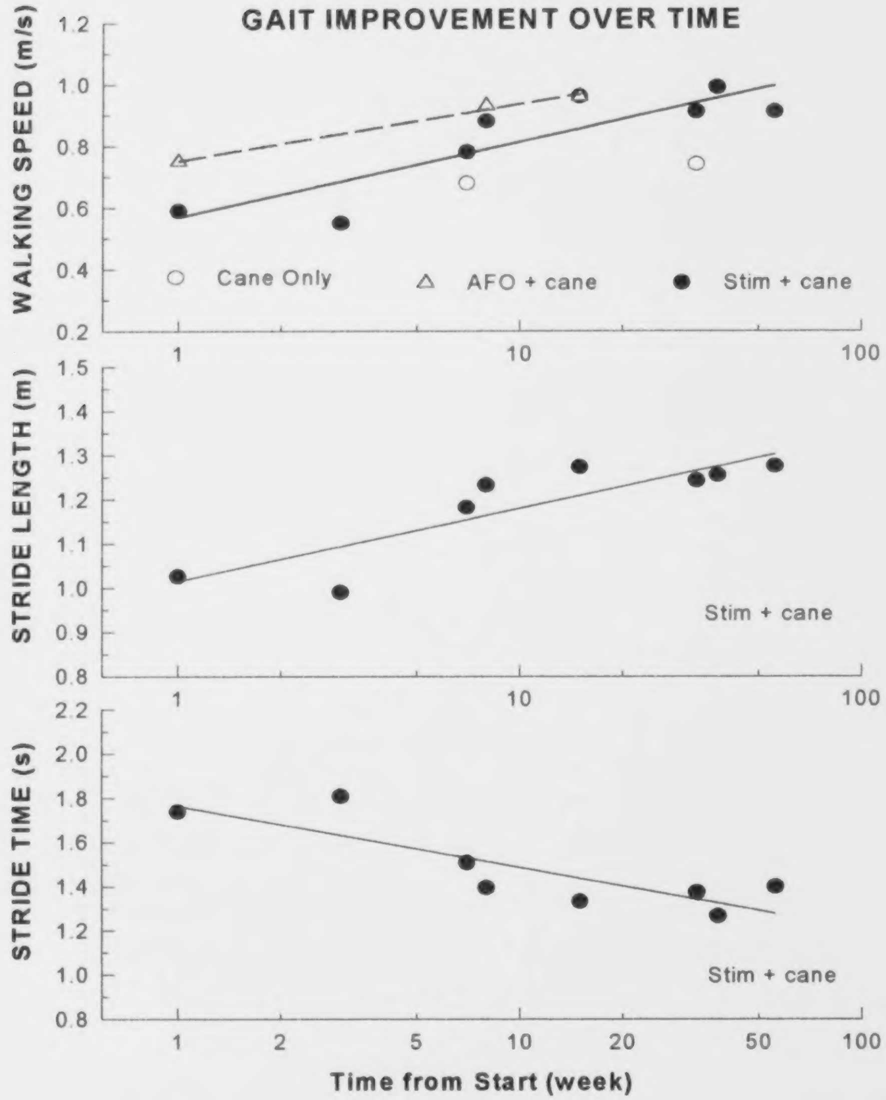


Figure 4-5. There is a significant increase in SA's walking speed both with or without FES, which is associated with both a significant increase in stride length and a significant decrease in stride cycle time. The figure also shows that the improvement of his gait parameters follows logarithmically the time course, characterized by a fast initial progress followed by a more smooth slope.

4.3.2 Subject LW

LW became quadriparetic after she suffered a cervical cord hematoma at C1/C2 level in 1986. She entered the FES program in January, 1990 and this is a follow up of her condition. Her gait problem and previous progress with the program was described in detail in a preceding report [6]. In brief, she had motor deficits of a typical incomplete quadriplegia and both her legs were weak. When standing she can step with her right foot but cannot break through the extensor spasticity of her left foot. About one year after recruitment into the FES program, she received an implanted telemetric peroneal nerve stimulator in her left side in August, 1990. Slow gait (<0.075 m/s) was elicited with hand switched stimulation. Further improvement was made with adding a FSR foot switch under her right foot which retains more voluntary control. When she shifted her weight onto her right foot before she intended to lift her left foot, the foot switch will automatically trigger the stimulation to the left. A simple four state rule base was applied to prevent the clonus causing misfiring. The use of automatic control was said not only to facilitate her gait but also her feeling of safety.

Her gait condition was worsened when she returned to the lab in early 1993. Developing clonus and weak TA muscle of the right side made her steps hard and her gait speed actually decreased as shown in Figure 4-6. A new drug treatment was started in October, 1993 to ease the clonus and spasticity. Gait analysis showed a moderate progress. On the FES side, it had been realized early that more channels of stimulation to several muscles would be helpful to improve her gait. As a second step, she received seven percutaneous electrodes in total for the CP nerve, Tibialis Anterior, quadriceps (VL) and gluteus medius muscles on her right side in December, 1993. With the percutaneous system, her walking speed reached 0.1 m/s for the first time after her injury. The clonus was reduced which was thought due to the sufficient stimulation intensity and more balanced stimulation to more than one muscle group with the percutaneous electrodes. An increase of hip flexion is also observed by comparing the gait analysis done before and after the percutaneous implantation.

LW represented the low end in terms of gait performance with an incomplete SCI. The overall speed increase over the period was not significant, but the benefit was. What was important was that FES was perceived as improving her gait quality and increasing her feelings of well being.

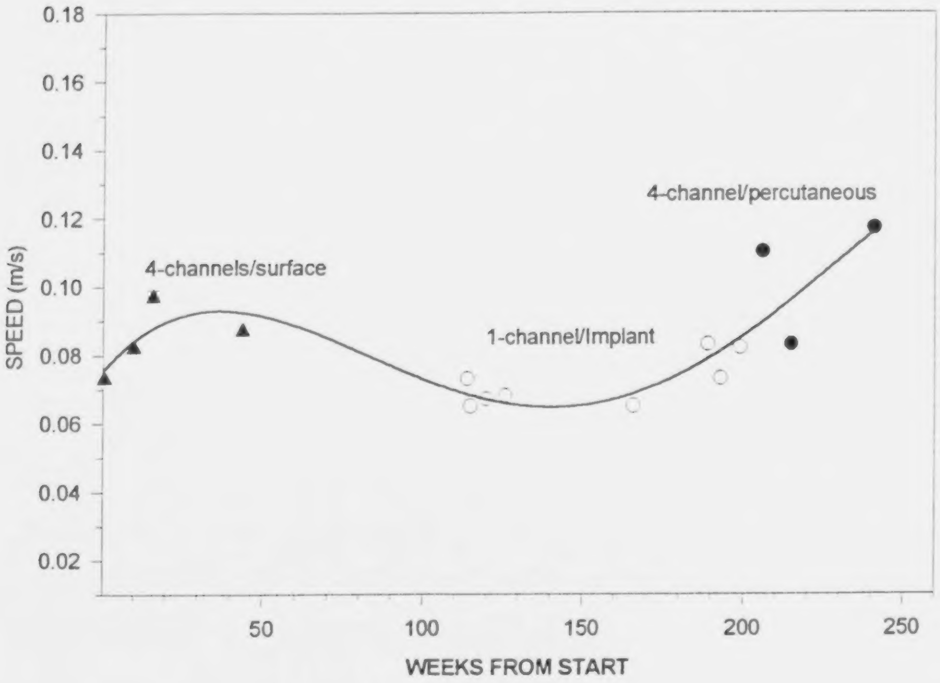


Figure 4-6. LW could walk slowly only with the help of FES to her left leg. Clonus and weak TA muscle of the right side reversed the gait improvement with the single channel implant. With the new drug treatment for clonus and spasticity and 4 channel FES system with percutaneous electrodes for the CP nerve, Tibialis Anterior, quadriceps (VL) and gluteus medius muscles, her walking speed reached 0.1 m/s for the first time after her injury.

4.3.3 Subject CE

CE was initially seen in March, 1994. She suffered a left stroke with residual weakness on her right side. Her upper extremity recovered to near normal functioning but she continues to have problems with her right leg. She uses one straight cane and an AFO due to weak dorsiflexion. During right swing she circumducts with minimal knee flexion. She was provided with a one channel surface stimulator (Mikro Fes, Ljubljana), initially using a hand switch for triggering which was quickly replaced by a heel switch. As shown in Table 4-3, her walking speed had an overall increase of 46% with an AFO, 34% with FES and 10% with a cane. However, the speed improvement with FES is not significant. This is probably because she had changed the stimulator several times. Figure 4-7 summarizes the gait improvement over the one year period. About 30 weeks after being in the program, she switched to using the WalkAid stimulator which is a below knee one piece device controlled by a built-in tilt sensor (Biomotion, Edmonton; see section 4.4.5 below). With this device, she felt that it was easier to put on and more comfortable to use than an AFO when she was walking outside her home. She also used it at home to assist her, for example, when going upstairs. Although she walked faster in average with an AFO during gait analysis, she preferred to use the WalkAid stimulator which she felt increased her gait quality and confidence. She continues to use the FES device on a daily base.

Table 4-3. Gait performance of CE

CONDITION	**FES**		**NO FES**		**BRACING**	
Stage	*INITIAL*	*FINAL*	*INITIAL*	*FINAL*	*INITIAL*	*FINAL*
Speed	0.49±0.02	0.66±0.10	0.52	0.57±0.02	0.56±0.06	0.82±0.03
Stride	0.85±0.02	1.01±0.07	0.87±	0.94±0.02	0.91±0.05	1.03±0.06
Cycle	1.76±0.03	1.54±0.15	1.69±	1.67±0.06	1.66±0.11	1.42±0.12

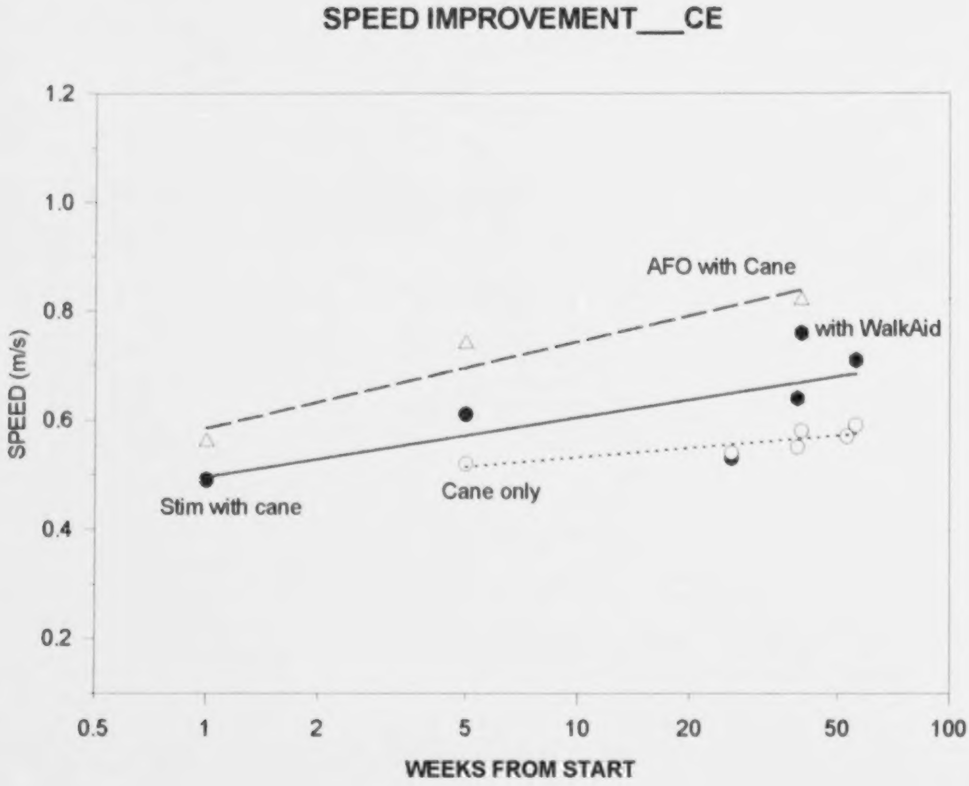


Figure 4-7. CE had an overall increase of 46% in walking speed with an AFO, 34% with FES and 10% with a cane. However, the improvement with FES is not significant, probably because she had been using different types of stimulators.

4.3.4 The population

Table 4-4 summarizes the three gait parameters recorded in the beginning of the program and those averaged for the measurements after the 6 month period for each subject. To see the significance level of intra-subject differences in the gait parameters independent Student's t-tests were performed on the data from the initial and final periods. With FES, there were significant increases in gait speed for subject CH, LS and SA; significant increases in stride length for CH and SA and significant decreases in stride cycle time for CC, LS and SA. Mean values of the initial and final walking speed for every subject are plotted as bar graphs shown in Figure 4-8 for a better comparison. Along with the program period, all subjects showed an increase in gait speed in each of the walking conditions, but the increase amount is marginally different among the subject population and under different walking conditions. Figure 4-9 gives the speed increase in terms of the initial walking speed, in which the improvement with FES increases with the subject's initial speed, ranging from 0.03 to 0.37 m/s. Due to the large inter-subject differences in the margin of improvement, and the small number of subjects, a paired Student's t-test for the subject group was not significant (P=0.06) for gait speed with FES, but was significant without FES (P=0.02). Two subjects used an AFO.

SPEED (m/s)

CONDITION	FES					NO FES					BRACING				
	INITIAL		*FINAL*		*T-test*	*INITIAL*		*FINAL*		*T-test*	*INITIAL*		*FINAL*		*T-test*
SUBJECT	Mean	S.D.	Mean	S.D.	P <	Mean	S.D.	Mean	S.D.	P <	Mean	S.D.	Mean	S.D.	P <
LW	0.07		0.10	0.02	0.50										
LS	0.26	0.03	0.30	0.02	0.05	0.25	0.01	0.27	0.03	0.50					
ND	0.33		0.27	0.04	0.02	0.33		0.25	0.00	0.02					
CH	0.39		0.46	0.07	0.05	0.36		0.45	0.07	0.05					
CC	0.43		0.51	0.00	0.20	0.42		0.46	0.03						
CE	0.49	0.02	0.66	0.10	0.50	0.52		0.57	0.02	0.05	0.56	0.06	0.82	0.03	0.05
SA	0.57*	0.03	0.94	0.05	0.01	0.68	0.05	0.74			0.75	0.06	0.96	0.02	0.02

STRIDE LENGTH (m)

CONDITION	FES					NO FES					BRACING				
	INITIAL		*FINAL*		*T-test*	*INITIAL*		*FINAL*		*T-test*	*INITIAL*		*FINAL*		*T-test*
SUBJECT	Mean	S.D.	Mean	S.D.	P <	Mean	S.D.	Mean	S.D.	P <	Mean	S.D.	Mean	S.D.	P <
LW	0.43		0.52	0.07	0.40										
LS	0.77	0.13	0.75	0.06	0.50	0.76	0.08	0.68	0.06	0.20					
ND	1.07		0.97	0.03	0.10	0.96		0.87	0.01	0.10					
CH	0.85		0.99	0.06	0.01	0.87		0.98	0.05	0.01					
CC	0.94		1.00	0.02	0.50	0.91		0.93	0.04						
CE	0.85	0.02	1.01	0.07	0.10	0.87		0.94	0.02	0.01	0.91	0.05	1.03	0.06	0.05
SA	1.01	0.03	1.26	0.02	0.00	1.09	0.04	1.12			1.17	0.01	1.23	0.02	0.10

STEP CYCLE (s)

CONDITION	FES					NO FES					BRACING				
	INITIAL		*FINAL*		*T-test*	*INITIAL*		*FINAL*		*T-test*	*INITIAL*		*FINAL*		*T-test*
SUBJECT	Mean	S.D.	Mean	S.D.	P <	Mean	S.D.	Mean	S.D.	P <	Mean	S.D.	Mean	S.D.	P <
LW	5.95		5.10	0.48	0.40										
LS	2.99	0.13	2.50	0.00	0.01	3.01	0.16	2.52	0.01	0.01					
ND	3.20		3.57	0.39	0.03	2.85		3.43	0.04	0.03					
CH	2.31		2.18	0.20	0.10	2.55		2.24	0.25	0.10					
CC	2.16		2.21	0.03	0.02	2.17		2.21	0.09						
CE	1.76	0.03	1.54	0.15	0.50	1.69		1.67	0.06	0.50	1.66	0.11	1.42	0.12	0.06
SA	1.77	0.05	1.35	0.07	0.01	1.59	0.06	1.50			1.57	0.14	1.29	0.01	0.02

Table 4-4. Gait performance of the population

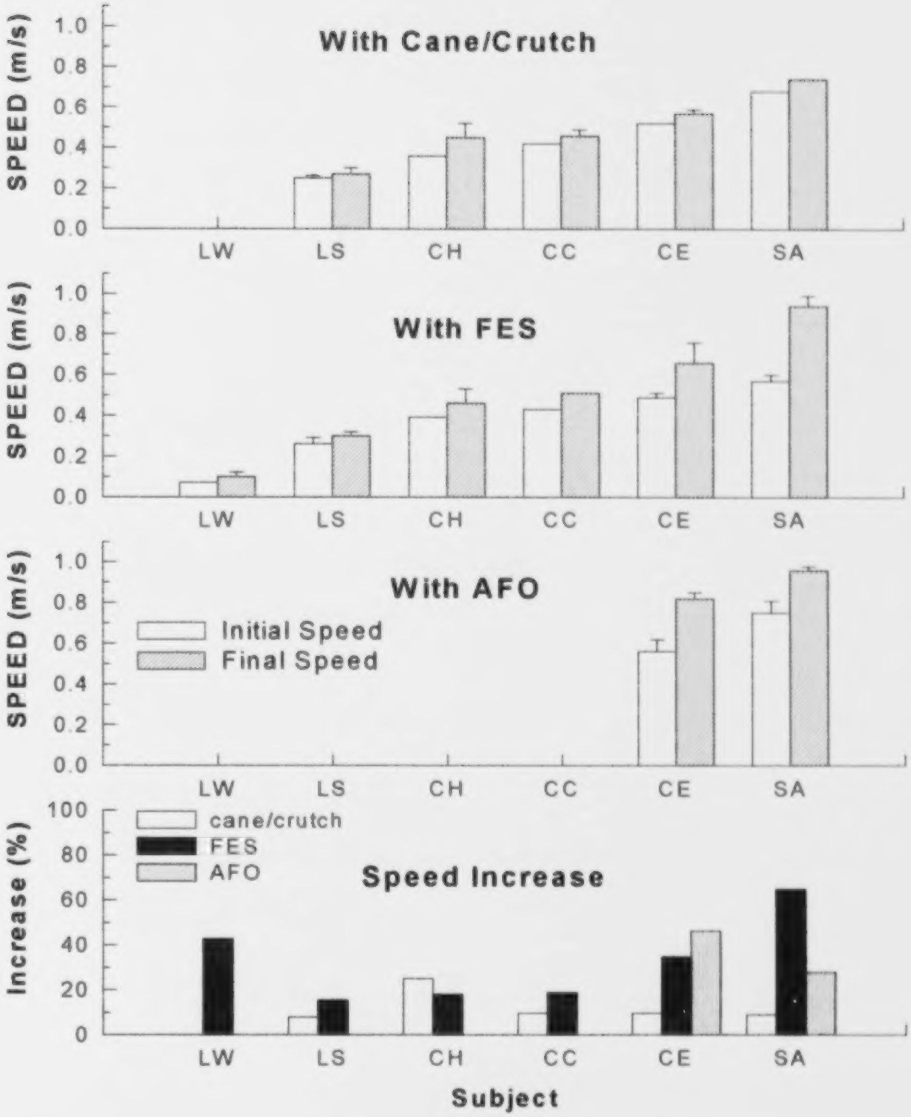


Figure 4-8. First three bar graphs show mean values and standard errors of the initial and final walking speed for every subject under different walking conditions. All subjects showed an increase in gait speed in each of the walking conditions over the program period. The last bar graph indicates that the speed improvement is marginally different among the subjects.

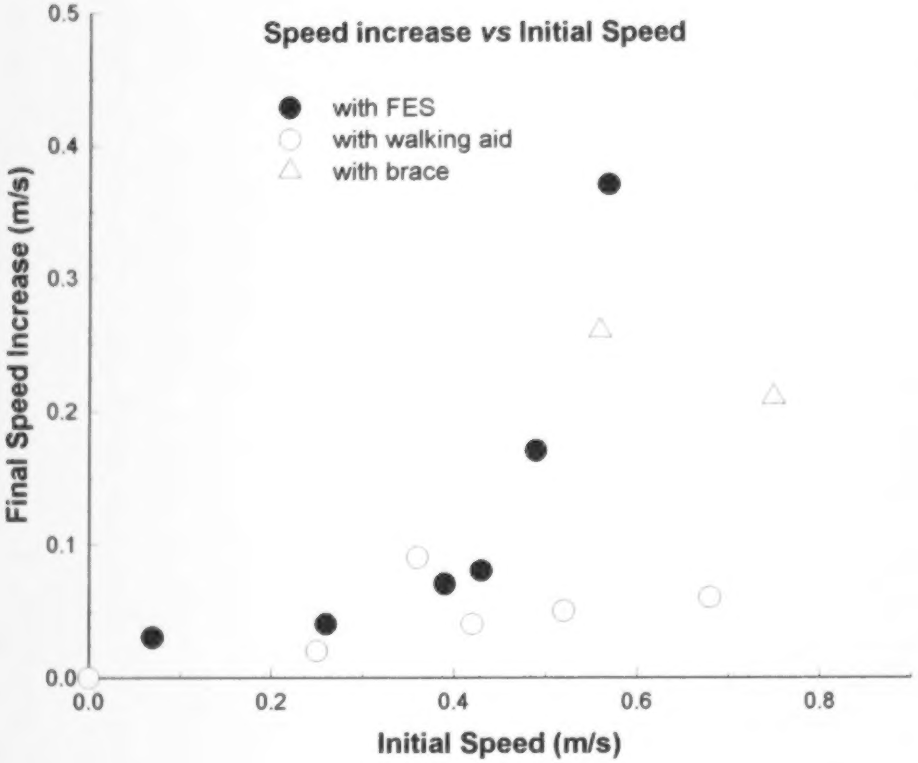


Figure 4-9. Trend shows that speed improvement in walking with FES is greater for subjects who have a greater initial walking speed. However, the improvement is not significant across the subject population. The increase in speed is significant for walking without using FES.

4.3.5 Preliminary results with the new foot drop stimulator

4.3.5.1 The stimulator

In responding to the complaints about device complexity that prevent them from being used regularly, we have designed an improved single channel stimulator. It is a fully self-contained single channel unit, as shown in Figure 4-10 its block diagram. The stimulator, the sensor, the battery and electrodes all fit in a comfortable, breathable garment that is contoured to fit snugly over the tibia. As a result the electrodes are automatically over the common peroneal nerve when the device is secured on the leg with Velcro straps. A tilt sensor (UA-1, Midori American Corp.) described in chapter 3 is built into the unit so that the stimulation is turned on when the leg leans forward and off when the leg leans backward. Two threshold settings on the panel let the subject adjust the appropriate triggering position. The self-fitting mechanical design allows the device to be placed on the tibia below the knee and the reusable electrodes at the fibula head over the peroneal nerve quickly. No other wire connection is needed in normal usage, but the device can alternatively use either a handswitch or a footswitch to control the stimulation. This option is useful when a new subject is determining the best stimulating spot in the first time. The stimuli are 25 Hz / 200 μs monophasic pulses with adjustable current ability up to 20 mA.

4.3.5.2 The subjects

Three female subjects respectively participated in the initial testing of the footdrop stimulator. Subject GC (A) was an incomplete SCI subject from Vancouver who showed hemiplegia, Subject CE (C) from Edmonton was previously described (see 4.4.3). They both had foot drop problem that prevented them from lifting up their affected feet easily during the swing phase. They used an AFO but were able to walk without any assistance at slow speed (0.3 and 0.6 m/s respectively). Subject TB (B) from Toronto had an incomplete SCI that resulted in hemiplegia.

She used a walker and an AFO to walk. Without an AFO, she could barely walk (at a speed less than 0.2 m/s).

4.3.5.3 Gait performance

The same method as described in section 4.3.3 is used to analyze the gait performance. For the subjects from Vancouver and Toronto, only video taped analysis was done.

Figure 4-11 shows the gait performance of three subjects in terms of gait speed, cycle time and stride length during the initial sessions. All three subjects showed improvement of gait performance when they walked with the FES device compared to no stimulation, and similar performance compared to an AFO which they had been using for a long time. The most dramatic improvement is seen in Subject A who had one year post stroke history. With the footdrop stimulator, she could walk at a near normal speed of 1 m/s in bare feet, compared to 0.28 m/s without using it. The increased gait speed, as we can see, came mainly from increased stride length. The use of double thresholds in the control protocol with tilt sensors also increases the noise tolerance level, which makes it even suitable for subjects with light clonus. Because of the better cosmesis and ease of use, the participating subjects prefer it to an AFO or footswitch, even when the gait improvement with the three methods was similar. Please note that the results shown are based on only a few trial sessions without a daily usage base. For a formal evaluation of the device, long term clinical trials are proceeding on a well defined population of stroke subjects [16].

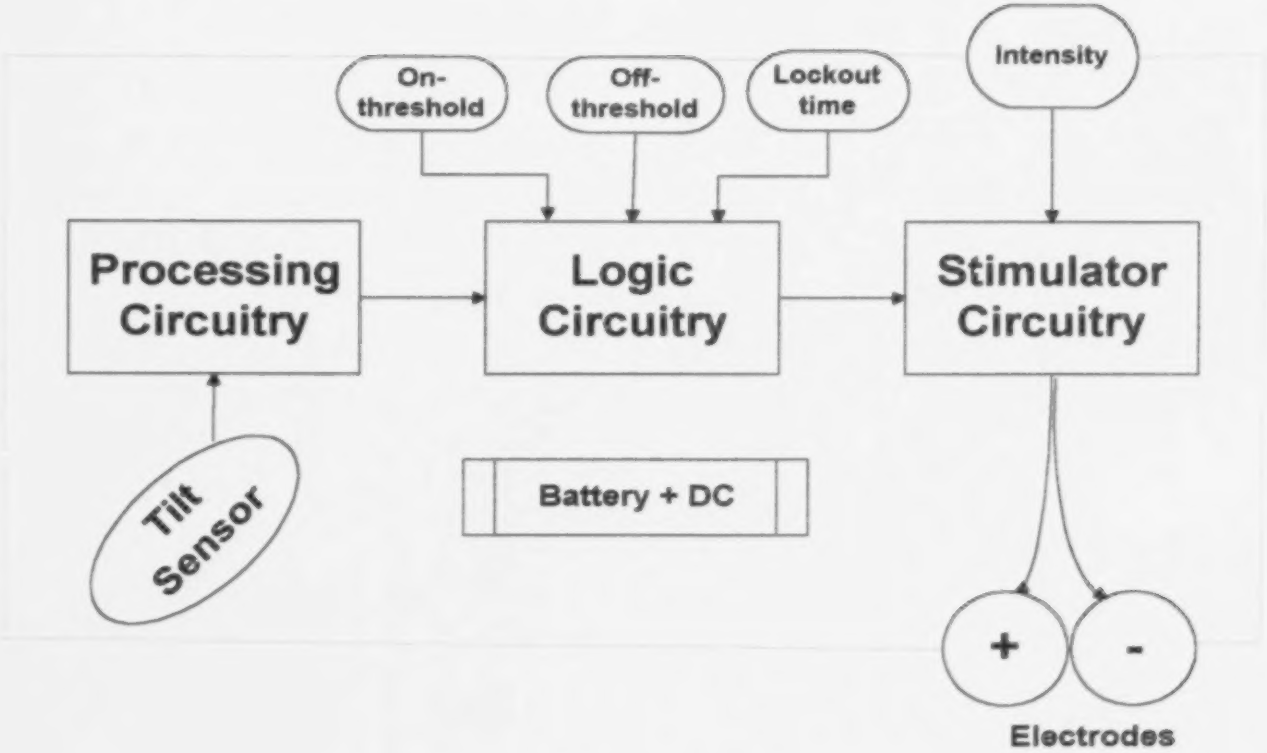

On-threshold
Off-threshold
Lockout time
Intensity
Processing Circuitry
Logic Circuitry
Stimulator Circuitry
Tilt Sensor
Battery + DC
+
-
Electrodes

Figure 4-10. Walkaid is a fully self-contained single channel stimulator. The stimulator, the sensor, the control circuitry, the battery and electrodes all fit in a comfortable, breathable garment that is contoured to fit snugly over the tibia. The stimulator ispositioned onto the tibia via a self-attaching holder with the active surface electrode over the peroneal nerve. No wiring and daily calibration is needed.

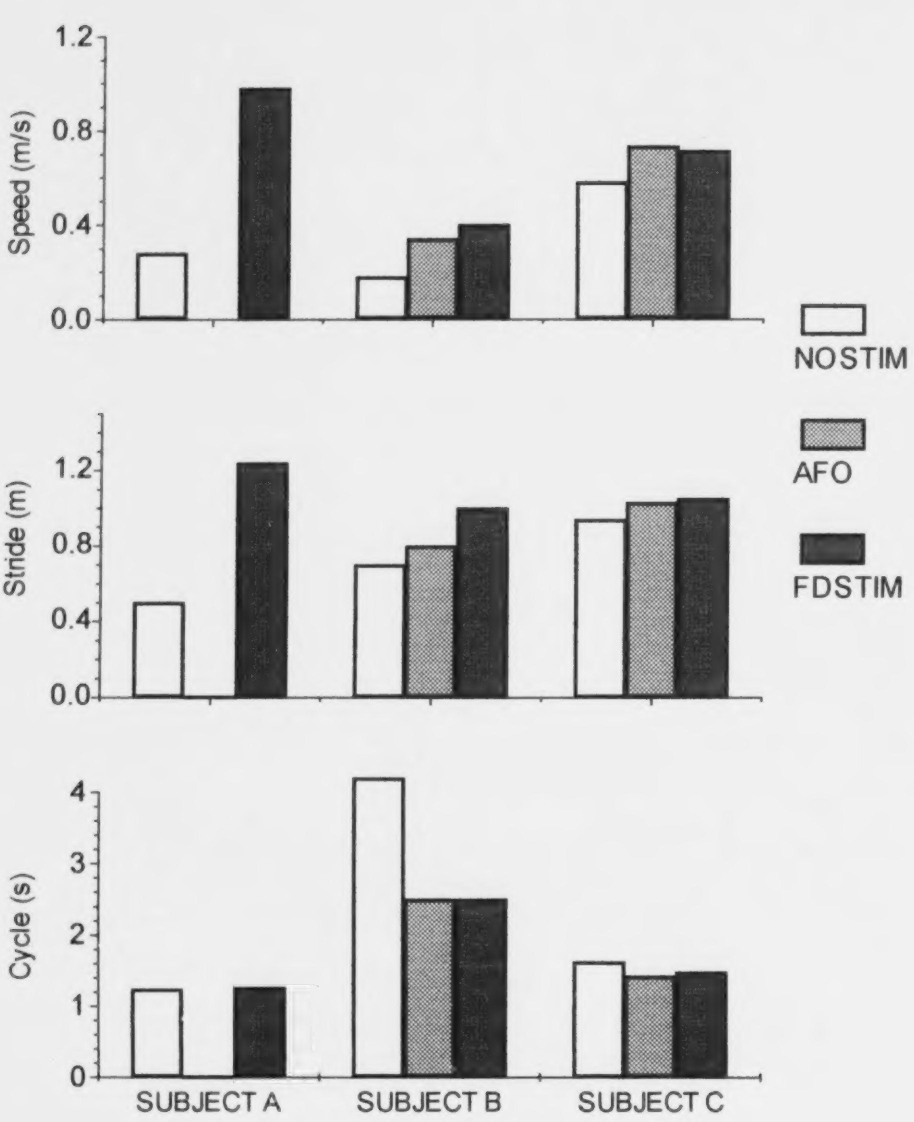


Figure 4-11. Gait performance of three subjects in terms of gait speed, cycle time and stride length during the initial sessions. In terms of walking speed between without aid and with FES, subject A had an improvement from 0.28 m/s to 0.98 m/s, subject B from 0.18 m/s to 0.4 m/s, and subject C from 0.58 m/s to 0.712 m/s. The improvement is similar to that achieved using an AFO. The speed improvement is seen as increased stride length and decreased stride time.

4.4 Discussion

This long-term multi-center clinical trial of FES for subjects with incomplete spinal cord injuries concentrated on the benefits in restoration of walking abilities using simple one to four channel FES systems. As part of the long-term study, the gait evaluation showed positive result for all the 6 subjects who had continued through the study course. Walking speed with FES increased on average 30% in the 6 subjects, 10% increase without FES in 5 of the subjects who can walk without FES, and 35% increase with AFO seen in the two subjects who used AFO. Although these increases were modest, they were significant for the subjects who had suffered an SCI at least two years prior to entering the study. Interest in their walking and some excitement to try new methods may had contributed to the increase over time, as well as the effects of muscle strengthening and general conditioning from walking. Among the studied subjects, there were no significant pattern reflecting the relation between the initial speed and the relative increase in final speed, although the direct improvement increases with the initial speed. Gait analysis indicated that the increase of walking speed was mainly contributed by the increase of the stride length. There was no significant changes found in the pattern of stance and swing time.

Subjects LW and SA both had multiple percutaneous electrodes implanted in the late stage of study period. For both subjects, adding stimulating channels besides the CP channel increased the walking speed and reduced the clonus. This improvement was thought to come from the increased and more balanced stimulation achieved by the percutaneous system. Percutaneous electrodes worked well with LW but they did not present the expected reliability for SA who had higher mobility. Wire breakage was the main reason.

Similar changes were seen over the entire subject population across the four centers [14]. The data were averaged over the normalized walking speed of each subject for the initial and final periods. On average there was more than 20% initial increase in speed when using FES and a further 20% increase over the period of use for a total increase in speed of nearly 50%. The effect of using a brace (AFO or KAFO) was also studied. The effect of FES was larger initially for those who did not use a brace, but the increase over time was similar as a whole. For many subjects, walking speed may not be the most important measure of the benefits from using FES. Therefore, we had a short questionnaire for each subject during the program for their subjective responses. Among the returned answers (21 out of 27 from four centers), over 90% thought they could walk better using FES, although objectively many did not show a significant increase in gait speed or decrease in energy consumption. All thought that the device helped them do things that were important to them and nearly all would like to continue using FES for walking. This investigation indicates that the general benefit of FES in this population is the increase of functionality and gait quality, while the actual acceptance level may depend on the tradeoff between the gain of functionality and the effort required to use it. Some subjects indicated that the device was not easy to use on a regular basis. Complaints included the difficulty in finding the sites for surface stimulation, particularly over the common peroneal nerve, which has been a perennial problem with surface FES systems, problems with leads and wires connection switches and electrodes to the stimulator. But there were no major hardware problems throughout the study except common items such as lead breakage.

FES has become an established treatment for gait abnormality and assistance for mobility of hemiplegic patients suffering from stroke, brain trauma and head injury, etc. [7]-[9]. The main device used has been single channel surface and implanted stimulators. The new footdrop stimulator eliminated the sensor wiring by using a tilt sensor as the control switch. The integrated design of the device allows ease of use and good cosmesis that greatly affect the acceptance of FES. With the decreasing cost of electronics, such a stimulator should cost little more than a custom-fitted AFO. Subject response from the early testing trials of the device is very encouraging. Gait improvement with the initial usage is comparable with using an AFO or footswitched stimulator. This invasive and low cost device therefore could be an alternative for a fully implanted peroneal stimulator. However, the control method used by the device is still confined to subjects who suffer mainly from foot drop but have some initial gait abilities with changing orientation of leg segments The question is therefore what percent of the patient population with footdrop or similar gait problems might benefit from using this device as an FES orthosis. Further clinical trials are proceeding in Edmonton.

With the good acceptance of the current generation of devices, that were used in the multi-center study and the development of more advanced, user friendly devices, it is safe to say that FES will find much more acceptance and application in treating incomplete spinal cord injuries and related motor problems that are found after stroke and head injury.

4.5 REFERENCES

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5. DISCUSSION AND CONCLUSIONS

Up to the present only simple control algorithms have been applied to FES systems for restoring gait, such as hand switches to initiate each step or preprogrammed sequences. These sequences are based on recorded average EMG patterns in normal individuals. Direct, computer control of electrical stimulation was proposed, emphasizing muscular properties and a discrete model for restoring functional locomotion. The use of feedback can improve the performance of FES systems. One feedback approach relies on sensing natural signals for control, while another uses artificial sensory feedback. The performance of FES systems with a feedback control system depends heavily on the quality of sensors.

Artificial sensors pose a number of problems when being used in FES systems. When used externally, they have problems such as donning, calibration, cosmesis, mechanical inconvenience and so on. When used for implantation, they are usually difficult to make, insufficiently bio-compatible and unable to provide signals without being powered. Natural sensors have been proposed as an alternative feedback signal source for FES. Recording nerve cuff electrodes have been developed and tested in animals and demonstrated to be feasible in humans for control of dorsiflexion in foot drop. The concept of using peripheral sensory nerve signals is attractive because an FES candidate is likely to have an intact peripheral nerve and receptor system, although broken from the higher center.

In chapter 2, we demonstrated in a chronic cat model that multi-electrode recordings from sensory nerves can provide satisfactory information for rule-based control. Recordings from two sensory nerves (tibial and SP) were sufficient to trigger the appropriate periods of stimulation reliably to ankle flexor and extensor muscles during the appropriate phases of walking. One important question with nerve cuff recording is how useful the whole nerve signals are for closed-loop control. Neuronal signals of single fibers are frequency-modulated all-or-none action potentials, while the whole nerve signals recorded with a cuff electrode reflect the fused neural activity of the largest fibers of the nerve. It is therefore reasonable to relate the whole nerve signals with the recruitment of fibers. This experiment showed that the envelope signals extracted with simple lowpass filtering contains sufficient information for rule-based control with threshold detection which requires low bits per sample in the feedback signals.

There are also a number of problems with the nerve cuff recording approach. They are invasive and need a complete implanted system to take full advantage of their potential, may cause nerve damage, and also have encapsulation and bio-compatibility problems. Another problem is that most research data come from animal models. When cuff electrodes are used in humans, cutaneous signals will differ when the subject wears shoes, socks etc., so that a more complicated signal processing technique is needed. With the advent of improved techniques in electrode design, materials and signal processing, the technical problems will likely be overcome and the nerve recording technique offers a promising potential in the control of FES.

In chapter 4, we showed that simple FES systems could improve the gait of subjects with an incomplete SCI or stroke. In simple FES systems such as peroneal stimulators, a robust, reliable and simple-to-use non-invasive external stimulator is no less attractive than an implantable system. In an effort to seek a wireless and robust sensor to replace the footswitch that causes problems such as wire breakage and bad cosmesis as is used by most current peroneal stimulators, we demonstrated in Chapter 3 the integration of a magnetoresistive tilt sensor into an peroneal FES device for correcting the foot drop. Tilt sensors provide control signals by detecting the absolute angular displacement of a leg segment. Unlike the foot switch method, tilt sensors eliminate the requirement to wear shoes, as well as being easy to don and doff. Our initial trials showed that tilt sensors can replace foot switches to control FES and prevent foot drop. This device with a tilt sensor promises a good cosmesis and ease of use with contact sensors.

Most of the participating subjects in the initial trials preferred it to an AFO or foot switch, even when the gait improvement with the three methods was similar. This non-invasive and low cost device therefore could be an alternative to a fully implanted peroneal stimulator. However, the control method used by the device is still confined to subjects who suffer mainly from foot drop and have some initial gait abilities with changing orientation of leg segments The response of this population to the device is still to be thoroughly tested through clinical trials.

The current version of tilt sensors being used are prone to breakage failure when subject to mechanical shock. This is because of its inherit mechanical structure. The newly available micro-machined integrated accelerometers with a DC response may provide a better alternative to providing the tilt signal in terms of mechanical reliability and potential to be implanted. The accelerometers, however, consume more source current than a magnetoresistive tilt sensor. This requires special power management techniques in order for it to be used in battery powered portable devices, which can be done by embedding a microcontroller.